Evaluation Report ERC2010-03

Thiencarbazone-methyl

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Overview

Registration Decision for Thiencarbazone

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, has granted conditional registration for the sale and use of Thiencarbazone-methyl Technical Herbicide, Velocity Herbicide and AE1162464 WG63 Herbicide, containing the technical grade active ingredient thiencarbazone, to control specific weeds in corn and wheat (spring and durum).

An evaluation of available scientific information found that, under the approved conditions of use, the products have value and do not present an unacceptable risk to human health or the environment.

Although the risks and value have been found acceptable when all risk reduction measures are followed, the applicant must submit additional scientific information as a condition of registration.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Thiencarbazone-methyl Technical Herbicide, Velocity Herbicide and AE1162464 WG63 Herbicide.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's *(a)* efficacy; *(b)* effect on host organisms in connection with which it is intended to be used; and *(c)* health, safety and environmental benefits and social and economic impact."

observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at www.hc-sc.gc.ca/cps-spc/pest/index-eng.php.

What Is Thiencarbazone-methyl?

Thiencarbazone-methyl is the active ingredient in the herbicide end-use products Velocity Herbicide and AE1162464 WG63 Herbicide. Velocity Herbicide is used to control or suppress several grass and broadleaf weeds in wheat (spring and durum). AE1162464 WG63 Herbicide is used to control redroot pigweed and green foxtail and suppress lamb's quarters in field corn.

Thiencarbazone-methyl inhibits the enzyme acetolactate synthase (ALS) in sensitive plants. Inhibition of this enzyme essentially starves the plants of essential amino acids, eventually leading to plant death.

Health Considerations

Can Approved Uses of Thiencarbazone-methyl Affect Human Health?

Thiencarbazone-methyl is unlikely to affect your health when used according to label directions.

Potential exposure to thiencarbazone-methyl may occur through the diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g., children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when thiencarbazone-methyl products are used according to label directions.

The technical grade active ingredient thiencarbazone-methyl was not acutely toxic. Consequently, no hazard statements are required on the technical product label.

The end-use product AE1162464 WG63 Herbicide was moderately irritating to the eye. Consequently, the statement "Warning - eye irritant" is required on the end-use product label.

The end-use product Velocity Herbicide was mildly irritating to the skin and moderately irritating to the eye. As a result, the label statement "Warning - skin and eye irritant" is required on the end-use product label.

Thiencarbazone-methyl was not genotoxic and there was no evidence of immunotoxicity or effects on the endocrine system. There was also no indication that thiencarbazone-methyl caused damage to the nervous system and there were no effects on reproduction or foetal development. The first signs of toxicity in animals given daily doses of thiencarbazone-methyl over longer periods of time were bladder and kidney effects. There was evidence of cancer in the urinary bladders of mice but only at doses where distinct precursor urinary tract changes were previously noted. Although these tumours were considered to be of limited relevance to humans, they are taken into account in the risk assessment. When thiencarbazone-methyl was given to pregnant animals, effects on the developing foetus were observed at doses that were toxic to the mother, indicating that the foetus is not more sensitive to thiencarbazone-methyl than the adult animal. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and water are not of concern

Aggregate chronic dietary intake estimates (food plus water) revealed that the general population and children (1 to 5 years old), the subpopulation which would ingest the most thiencarbazone-methyl relative to body weight, are expected to be exposed to less than 0.1% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from thiencarbazone-methyl is not of concern for all population sub-groups.

Animal studies revealed no acute health effects. Consequently, a single dose of thiencarbazone-methyl is not likely to cause acute health effects in the general population (including infants and children).

The *Food and Drugs Act (FDA)* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for FDA purposes through the evaluation of scientific data under the *Pest Control Products Act (PCPA)*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout Canada and the United States using thiencarbazone-methyl on corn and wheat crops were acceptable. The MRLs for this active ingredient can be found in the Science Evaluation section of this Evaluation Report.

Occupational Risks From Handling AE1162464 WG63 Herbicide and Velocity Herbicide

Occupational risks are not of concern when AE1162464 WG63 Herbicide and Velocity Herbicide are used according to the proposed label directions, which include protective measures.

Farmers and custom applicators who mix, load or apply AE1162464 WG63 Herbicide to corn or Velocity Herbicide to wheat, as well as field workers re-entering freshly treated fields, can come in direct contact with thiencarbazone-methyl residues on the skin. Therefore, the labels specify that anyone mixing/loading and applying AE1162464 WG63 Herbicide or Velocity Herbicide must wear long sleeves, long pants and shoes plus socks. During mixing/loading, clean up and equipment repair, chemical resistant gloves must also be worn. The labels also require that workers do not enter treated fields for 12 hours after application. Consideration of these label statements, the number of applications and the expected exposure period for handlers and workers, indicated that the risks to these individuals are not a concern.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Thiencarbazone-methyl Is Introduced Into the Environment?

Thiencarbazone-methyl enters the environment when used as a herbicide on corn and wheat.

In the terrestrial environment, thiencarbazone-methyl undergoes biotransformation resulting in four major transformation products. Thiencarbazone-methyl and three of the transformation products are slightly persistent in soil while one of the transformation products is persistent. Thiencarbazone-methyl and its transformation products do not bind to soil particles and have potential for leaching to groundwater or for runoff to surface water.

In the aquatic environment, thiencarbazone-methyl undergoes biotransformation resulting in five transformation products. Thiencarbazone-methyl does not persist in aquatic systems. One of the transformation products is moderately persistent in water and sediment. Two of the transformation products are moderately persistent in water. One of the transformation products is not persistent in water and sediment while another is moderately persistent and is only formed under anaerobic conditions.

Based on its low volatility, thiencarbazone-methyl residues are not expected in air.

Thiencarbazone-methyl and its relevant transformation products pose negligible risk to earthworms, bees, birds, beneficial arthropods, small wild mammals, aquatic invertebrates, mollusks, amphibians, or fish, when used as proposed.

Thiencarbazone-methyl poses a risk to aquatic plants and algae and terrestrial plants. To minimise the risk from exposure via spray drift, buffer zones of 1 - 30 metres (depending on end-use product and application equipment) are required to protect nearby plants.

Value Considerations

What Is the Value of Thiencarbazone-methyl

Thiencarbazone-methyl, a post-emergence herbicide, controls a broad spectrum of grassy and broadleaved weeds in wheat (spring and durum) and field corn.

A single application of thiencarbazone-methyl provides effective control of numerous grassy and broadleaved weeds, including wild oat and green foxtail, in wheat (spring and durum) and field corn. Thiencarbazone-methyl is compatible with integrated weed management practices, conservation tillage, and conventional crop production systems. Since thiencarbazone-methyl is applied after weed emergence, growers are able to assess whether the herbicide is suitable for the particular weed species present.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the labels of Velocity Herbicide and AE1162464 WG63 Herbicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

As there is a concern with users coming into direct contact with AE1162464 WG63 Herbicide or Velocity Herbicide on the skin, anyone mixing, loading and applying AE1162464 WG63 Herbicide or Velocity Herbicide must wear long sleeves, long pants and shoes plus socks. During mixing/loading, clean up and equipment repair, chemical resistant gloves must also be worn. In addition, standard label statements to protect against drift during application were added to the label.

Environment

To minimise the risk to terrestrial plants, aquatic plants and algae from exposure to thiencarbazone-methyl via spray drift, buffer zones of 1-30 metres (depending on end-use product and applic tion equipment) are required.

What Additional Scientific Information Is Being Requested?

Although the risks and value have been found acceptable when all risk-reduction measures are followed, the applicant must submit additional scientific information as a condition of registration. More details are presented in the Science Evaluation of this Evaluation Report or in the Section 12 Notice associated with these conditional registrations. The applicant must submit the following information by September 30, 2010.

Human Health

Final storage stability report (18 months)

Sample extraction and analysis dates for all samples from the wheat Crop Field Trial (CFT) to ensure that the analysis was completed within the period of demonstrated freezer stability.

Value

Tank mixes: an additional three trials are required for the tank mix of Velocity + Refine DF + 2,4-D ester in spring wheat without Agral 90. At least two trials should be taken to yield. An additional three trials are required for each of the tank mixes in durum wheat (Velocity + 2,4-D ester, Velocity + MCPA ester, and Velocity + Infinity). At least two trials for each tank mix should be taken to yield.

Rotational crops: an additional two trials in chickpea are required, with at least one taken to yield. An additional four trials in lentils are required, with at least two taken to yield. An additional three trials in timothy are required, with at least one taken to yield.

Other Information

As these conditional registrations relate to a decision on which the public must be consulted,[3] the PMRA will publish a consultation document when there is a proposed decision on applications to convert the conditional registrations to full registrations or on applications to renew the conditional registrations, whichever occurs first.

[3] As per subsection 28(1) of the *Pest Control Products Act*.

The test data cited in this Evaluation Report (i.e. the test data relevant in supporting the registration decision) will be made available for public inspection when the decision is made to convert the conditional registrations to full registrations or to renew the conditional registrations (following public consultation). If more information is required, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

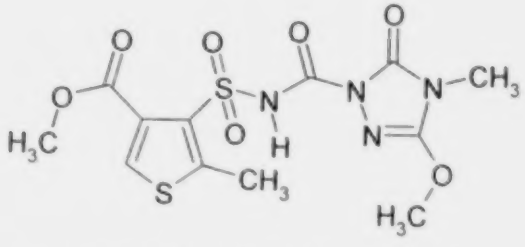
Science Evaluation

Thiencarbazone-methyl

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Thiencarbazone-methyl
Function	Herbicide
Chemical name	
1. **International Union of Pure and Applied Chemistry (IUPAC)**	Methyl 4-({[(3-methoxy-4-methyl-5-oxo-4,5-dihydro-1H-1,2,4-triazol-1-yl)carbonyl]amino}sulfonyl)-5-methylthiophene-3-carboxylate
2. **Chemical Abstracts Service (CAS)**	3-Thiophenecarboxylic acid, 4-[[[(4,5-dihydro-3-methoxy-4-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl)carbonyl]amino]sulfonyl]-5-methyl-, methyl ester
CAS number	317815-83-1
Molecular formula	$C_{12}H_{14}N_4O_7S_2$
Molecular weight	390.4
Structural formula	



Purity of the active ingredient	97.6% nominal (limits 95.0% - 100.0%)

1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Product

Technical Product—Thiencarbazone-methyl Technical Herbicide

Property	Result
Colour and physical state	Light yellow powder
Odour	No characteristic odour
Melting range	190°C to 223°C
Boiling point or range	No boiling point at atmospheric pressure
Specific gravity	1.52
Vapour pressure at 20°C	8.8×10^{-14} Pa
Henry's law constant at 20°C	pH 4 2.00×10^{-13} $Pa \cdot m^3 \cdot mol^{-1}$ pH 7 7.88×10^{-14} $Pa \cdot m^3 \cdot mol^{-1}$ pH 9 8.24×10^{-14} $Pa \cdot m^3 \cdot mol^{-1}$ in water pH 3.9 4.77×10^{-13} $Pa \cdot m^3 \cdot mol^{-1}$
Ultraviolet (UV)-visible spectrum	□ (nm) ε ($l.mol^{-1}.cm^{-1}$) 214 28596.07 234 14057.94
Solubility in water at 20°C	pH 4 172 mg/L pH 7 436 mg/L pH 9 417 mg/L In distilled water pH 3.9 72 mg/L
Solubility in organic solvents at 20°C (g/L)	Solvent Solubility ethanol 0.23 n-hexane 0.00015 toluene 0.91 dichloromethane 100 - 120 acetone 9.54 ethylacetate 2.19 dimethyl sulfoxide 29.15
n-Octanol-water partition coefficient (*K*ow)	K_{OW} $\log K_{OW}$ pH 4 0.738 -0.13 pH 7 0.010 -1.98 pH 9 0.0073 -2.14
Dissociation constant (p*K*a)	pKa = 3.0
Stability (temperature, metal)	Stable in the presence of metals and metal ions.

End-Use Product--Velocity Herbicide

Property	Result
Colour	Opaque brown
Odour	Mild aromatic solvent odour
Physical state	Viscous liquid
Formulation type	Suspension
Guarantee	Thiencarbazone-methyl.....10 g/L nominal (9.0 g/L - 11.0 g/L)
Container material and description	HDPE (high density polyethylene containers) 1L to bulk
Density	1.012 g/mL
pH of 10% dispersion in water	8.9
Oxidizing or reducing action	The product does not contain any oxidizing or reducing agents.
Storage stability	The product is stable when stored for one year at ambient warehouse temperature in commercial packaging.
Corrosion characteristics	The product is not corrosive to the packaging material.
Explodability	No components have any explosive properties.

End-Use Product--AE1162464 WG63 Herbicide

Property	Result
Colour	Light tan
Odour	Mild sweet odour
Physical state	Solid
Formulation type	Wettable granules
Guarantee	Thiencarbazone-methyl.....21% nominal (20.4% - 21.6%)
Container material and description	HDPE (high density polyethylene containers) 1kg to bulk
Density	0.51 - 0.67 g/cm^3
pH of 1 0% dispersion in water	4.37
Oxidizing or reducing action	The formulation does not contain any oxidizing or reducing agents.
Storage stability	The product is stable when stored for one year at ambient warehouse temperatures in commercial packaging.
Corrosion characteristics	The product is not corrosive to the packaging material.
Explodability	No components have any explosive properties.

1.3 Directions for Use

1.3.1 Velocity Herbicide

Velocity Herbicide is a selective herbicide for use as a post-emergence treatment on wheat (spring and durum), for the control of grassy and broadleaved weeds. The product is applied once per growing season at a rate of 5 g a.i./ha as a broadcast treatment with either ground or aerial application equipment to control the weeds listed below.

Weed Control Claims for Velocity Herbicide

Herbicide Rate	Weeds Controlled	Weeds Suppressed
5 g a.i./ha or 0.5 L product/ha	Wild oats, green foxtail, barnyard grass, wild mustard, redroot pigweed, stinkweed, shepherd's purse, hemp-nettle, volunteer canola*, cleavers, pale smartweed, wild buckwheat,	Yellow foxtail, Persian darnel, lamb's quarters, Russian thistle

* non-ALS tolerant

1.3.2 AE1162464 WG63 Herbicide

AE1162464 WG63 Herbicide is a selective herbicide for use as a post-emergence treatment on field corn, for the control of grassy and broadleaved weeds. The product is applied once per growing season at a rate of 7.5 g a.i./ha as a broadcast treatment with ground application equipment to control the weeds listed below.

Weed Control Claims for AE1162464 WG63 Herbicide

Herbicide Rate	Weeds Controlled	Weeds Suppressed
7.5 g a.i./ha (72 g product/ha) + 0.25% v/v Agral 90 + 2.5 L/ha 28% UAN	Redroot pigweed, green foxtail	Lamb's quarters

1.4 Mode of Action

Thiencarbazone-methyl belongs to the chemical family of sulfonylaminocarbonyltriazolinones, and obtains its herbicidal activity through the inhibition of the enzyme acetolactate synthase (ALS) in sensitive plants. ALS is a key enzyme in the biosynthetic path leading to the branched-chain amino acids valine, leucine and isoleucine. Branched-chain amino acids belong to the group of essential amino acids that cannot be synthesized in mammals; consequently, the enzyme ALS is not present in mammals. Thiencarbazone-methyl is regarded as a Group 2 (Weed Science Society America group) or Group B (Herbicide Resistance Action Committee) herbicide (refer to Regulatory Directive DIR99-06, Voluntary Pesticide Resistance Management Labelling Based on Target Site/Mode of Action).

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredient and the impurities in Thiencarbazone-methyl Technical Herbicide have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The methods provided for the analysis of the active ingredients in all formulations have been validated and assessed to be acceptable for use as enforcement analytical methods.

2.3 Methods for Residue Analysis

2.3.1 Soil, Sediment and Water Matrices

High-performance liquid chromatography methods with tandem mass spectrometry (HPLC-MS/MS) were developed and proposed for data generation and enforcement purposes. These methods fulfilled the requirements with regards to selectivity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries (70-120%) were obtained in soil, sediment and water matrices. Methods for residue analysis are summarized in Appendix I, Table 1.

2.3.2 Plant and Animal Matrices

High Performance Liquid Chromatography tandem Mass Spectrometry (HPLC-MS/MS) methods 00963 and 01022 were developed and proposed for data generation and enforcement purposes for plant and animal matrices, respectively. As well, methods 00962 and 00990 were developed and proposed for data generation purposes for plant and animal matrices, respectively. These methods fulfilled the requirements with regards to specificity, accuracy and precision at the respective method limit of quantitation (0.01 ppm for each analyte). Acceptable recoveries (70-120%) were obtained in plant and animal matrices. Adequate extraction efficiencies were demonstrated using radiolabelled wheat forage, straw and grain as well as milk, muscle, fat, liver

and kidney analyzed with the enforcement methods. Multi Residue Methods were tested but are not adequate to analyze for thiencarbazone-methyl and the metabolites associated with it. Methods for residue analysis are summarized in Appendix I, Table 1.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A detailed review of the toxicological database for thiencarbazone-methyl was conducted. The database is complete, consisting of the full array of toxicity studies currently required for hazard assessment purposes. The studies were carried out in accordance with currently accepted international testing protocols and Good Laboratory Practices. The scientific quality of the data is high and the database is considered adequate to define the majority of the toxic effects that may result from exposure to this chemical pest control product.

Thiencarbazone-methyl was of low acute toxicity by the oral, dermal and inhalation routes of exposure in Wistar rats. It was non-irritating to the skin and minimally irritating to the eyes of New Zealand White rabbits. Thiencarbazone-methyl was negative for skin sensitization using the Guinea Pig Maximization method.

AE1162464 WG63 Herbicide was of low acute toxicity by the oral, dermal and inhalation routes of exposure in Sprague Dawley rats. It was non-irritating to the skin and moderately irritating to the eyes of New Zealand White rabbits. AE1162464 WG63 Herbicide was negative for skin sensitization using the Guinea Pig Buehler method.

Velocity Herbicide was of low acute toxicity by the oral and dermal routes and slightly toxic by the inhalation route of exposure in Sprague Dawley rats. It was mildly irritating to the skin and moderately irritating to the eyes of New Zealand White rabbits. Velocity Herbicide was negative for skin sensitization using the Local Lymph Node Assay (LLNA) method.

In metabolism studies performed in rats, approximately 92-100% of the administered dose (AD) was recovered. Absorption was rapid (Tmax = 0.6-1 hours). Approximately 42-55% of the AD was absorbed. Area under the curve (AUC) values were proportional to dose. Elimination included a fast initial phase ($t_{1/2}$ = 0.12-0.55 hours) and a slower terminal phase ($t_{1/2}$ = 8-36 hours). Approximately 87-97% (low dose) and 73% (high dose) of the AD was excreted within 24 hours post-dosing, with excretion nearly complete (99%) within 48 hours. Urinary and fecal excretion accounted for 42-54% and 44-58% of the AD, respectively. Excretion via the bile (1.4%) and expired air (0.01%) was negligible.

Quantitative whole body autoradiography revealed the highest levels of radioactivity (µg/g) in the liver, blood, kidney, lung, adrenal gland, myocardium, brown fat, skin, salivary gland, pineal body, thyroid gland, and pituitary gland at 1 hour post-dosing. After 7 days, all values were below the limit of detection, except for the nasal mucosa (both labels) and the liver and testes (thiophene-label only), which had very low concentrations.
The parent compound underwent limited metabolism and was the major component in excreta (81-92% of the AD). For the thiophene label, one minor metabolite (thiencarbazone-methyl-

sulfonamide-carboxylic acid; 1-2%) and one trace metabolite (thiencarbazone-methyl-thienesaccharine; 0.1-0.2%) were detected in urine. Only the parent was detected in feces and bile. BYH-18636-sulfonamide was identified as a tentative metabolite in urine and feces (0.7-1.5%), but was also present in trace amounts in the dosing suspensions. For the dihydrotriazole label, 5 trace metabolites (<1%) were identified: methyl carbamate, thiencarbazone-methyl-OMT, thiencarbazone-methyl-MMT and 2 unknowns.

[Thiophene-4-^{14}C] thiencarbazone-methyl was metabolized through hydrolysis resulting in cleavage of the urea group and release of the thiophene-sulfonamide moiety. A second hydrolysis of the methyl ester occurred, yielding thiencarbazone-methyl-sulfonamide-carboxylic acid, which in turn was cyclized to thiencarbazone-methyl-thieno-saccharine, forming a new sulfonamide bond. [Dihydrotriazole-3-^{14}C] thiencarbazone-methyl was metabolized by hydrolysis resulting in cleavage of the urea group and the formation of BYH-18636-MMT. Desmethylation of thiencarbazone-methyl-MMT led to thiencarbazone-methyl-OMT and subsequent cleavage of the triazolinone moiety to methyl-carbamate.

A waiver was granted for the short-term dermal rat study, based on the low dermal toxicity and lack of irritation potential after acute exposure, limited dermal absorption and availability of appropriate NOAELs from the short-term oral studies with thiencarbazone-methyl.

In the short-term oral toxicity studies the target organs were the bladder (all species) and the kidney (rat and dog). Bladder effects included calculi in the bladder, inflammatory changes, haemorrhage and epithelial and urothelial hyperplasia. Kidney effects included intrapelvic eosinophilic urolithiasis and collecting duct hyperplasia. In the long-term mouse toxicity study, bladder effects became more severe and included an increase in incidence of stones and histopathology such as urothelial hyperplasia, interstitial edema, suburothelial mixed cell infiltrate, intramuscular inflammatory cell infiltrate, serosal mixed cell infiltrate, induced arteritis and adenomysosis. In the long-term rat study, an increased incidence of crystals was observed in the bladder.

Thiencarbazone-methyl was determined to be non-genotoxic in both the in vitro and in vivo mutagenicity studies. There was no evidence of carcinogenic potential for thiencarbazone-methyl in the rat. The dose levels chosen for the rat study did not reach the maximum tolerated dose (MTD); however, based on the kidney effects which were observed in the short-term rat studies, the dosing was considered adequate. In contrast, the mouse study, which did reach MTD, showed an increase in incidence of M-transitional cell carcinoma and B-transitional cell papilloma in the bladder. A mode of action (MOA) framework was used to evaluate the applicability of animal urinary tract tumour data to human risk assessment. A clear description of the key events, with dose and temporal relationships was presented; however, the reversibility of urinary tract lesions after treatment with thiencarbazone-methyl was not investigated. No additional mechanistic studies were submitted. Urinary bladder tumours in mice only occurred in the presence of other urinary tract effects after long-term exposures to doses that produced precipitation of the test substance and generation of urinary crystals/calculi. Calculi were only present at the highest dose tested, but crystals were occasionally present in the urine of mid-dose animals. The low dose was consistently negative for crystals, calculi and other treatment-related effects in the urinary tract. Chemical analysis of urinary tract calculi obtained from

thiencarbazone-methyl treated mice confirmed that the stones were predominantly comprised of the parent compound. Many chemicals such as uracil, melamine, saccharin and others have been identified which fit within this MOA framework. Based on the lack of genotoxicity, the well known biology and toxicology of urinary tract calculi, anatomical differences between rodents and humans, and the lack of carcinogenic effect of related sulfonamide drugs in humans (even at doses that cause formation of sulfonamide crystals in the urinary tract) (Clayson, 1974; Robinson and MacDonald, 2001; Schaeffer and Schaeffer, 2007), thiencarbazone-methyl is not expected to pose a carcinogenic risk to humans at low exposure levels.

There was no evidence of increased susceptibility of the young following in utero or early life exposure to thiencarbazone-methyl. In the rat and rabbit developmental toxicity studies, fetal weights were decreased in both species. Additionally, rabbits produced an increased incidence of runts and rat fetuses showed retarded ossification of several bones and wavy ribs. The dams of both species had decreased food consumption and body weight gain and increased sediment in the urinary bladder and/or kidney. Maternal rabbits had decreased faeces and the maternal rat had an increased incidence of urethra and kidney dilation. In a two-generation reproductive toxicity study, kidney and urinary bladder stones with pelvic dilation were seen in the offspring. In the parental groups there was an increased incidence of tilted head, emaciation and kidney stones with pelvic dilation were observed. Also noted were increased urination and kidney weight plus decreased body and liver weight. There was no indication of reproductive toxicity.

No evidence of neurotoxicity was observed in either the acute or subchronic neurotoxicity studies in rats. No treatment-related clinical signs indicative of neurotoxicity were observed in short-term or long-term exposure studies in rats, mice, or dogs. Therefore, it was concluded that thiencarbazone-methyl is not a neurotoxicant.

Acute oral toxicity, genotoxicity and short-term dietary rat studies were submitted for the carboxylic acid (M01), sulfonamide (M15) and N-desmethyl (M07) thiencarbazone-methyl metabolites. The M01 and M15 metabolites are present in soil, plants, hens and goats, with the latter identified as a tentative metabolite in the rat. The M07 metabolite is also present in plants, hens and goats, but is not a product of rat metabolism. In all three cases, the acute oral toxicity was minimal, the genotoxicity was negative and the short-term studies showed no adverse effects at the highest dose tested. Based on these findings, the thiencarbazone-methyl metabolites were not considered to be more toxic than the parent.

Results of the acute and chronic tests conducted on laboratory animals with Thiencarbazone-methyl Technical Herbicide and its associated end-use products, along with the toxicology endpoints for use in the human health risk assessment, are summarized in Appendix I ,Tables 2, 3, and 4

3.1.1 PCPA Hazard Characterization

For assessing risks from potential residues in food or from products used in or around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to take into account completeness of the data and potential prenatal and postnatal toxicity with respect to the exposure of and toxicity to infants and children. A different factor may be determined to be appropriate on the basis of reliable scientific data.

With respect to the completeness of the toxicity database as it pertains to the exposure of and toxicity to infants and children, extensive data were available for thiencarbazone-methyl with respect to the toxicity to infants and children and consisted of rabbit and rat developmental toxicity studies and a 2-generation rat reproduction study. In the developmental toxicity studies with thiencarbazone-methyl, treatment-related decreased fetal weights, retarded ossification of several bones including metacarpals, sternebrae, sacral and caudal vertebrae and phalanges and wavy ribs were observed in rats, and decreased fetal weight and increased incidence of runts were observed in rabbits in the presence of maternal toxicity. In the 2-generation reproductive toxicity study, treatment-related clinical signs, kidney stones with pelvic dilatation, one mortality, decreased liver and body weights, and increased kidney weights were noted in offspring at maternally toxic doses. Concern for these findings was offset by the fact that they occurred at high doses. There was no indication of increased susceptibility in fetuses or offspring compared to adults in the developmental or reproductive toxicity studies. On the basis of this information, the 10-fold PCPA factor was reduced to 1-fold.

3.2 Determination of Acute Reference Dose

An acute reference dose (ARfD) for thiencarbazone-methyl was not determined because an endpoint of concern attributable to a single exposure was not identified in the oral toxicity studies.

3.3 Determination of Acceptable Daily Intake

The recommended acceptable daily intake (ADI) for thiencarbazone-methyl is 1.17 mg/kg bw/day based on the NOAEL of 117 mg/kg bw/day in the 12 month dog study. The NOAEL was based on increased mean urinary protein, calculi and abnormal consistency noted in the urinary bladder along with slight to moderate transitional cell hyperplasia, slight congestion, and slight haemorrhage in the bladder and decreased body weight gain the first 56 days of the study at the LOAEL of 179 mg/kg bw/day. The standard uncertainty factor of 100 is required to account for interspecies extrapolation (10-fold) as well as intraspecies variability (10-fold). Further to the discussion in the PCPA Hazard Consideration section above, there was no indication of serious effects or increased susceptibility in the offspring compared to parental animals in the two-generation reproduction study and developmental studies. On the basis of this information, the 10-fold PCPA factor was reduced to 1-fold, resulting in a composite assessment factor (CAF) of 100-fold.

The ADI is calculated according to the following formula:

$$ADI = \frac{NOAEL}{CAF} = \frac{117 \text{ mg/kg bw}}{100} = 1.17 \text{ mg/kg bw of thiencarbazone-methyl}$$

3.4 Occupational and Residential Risk Assessment

3.4.1 Toxicological Endpoints

Occupational exposure to AE1162464 WG63 Herbicide or Velocity Herbicide is characterized as short -term and is predominantly by the dermal route.

The NOAEL of 149 mg/kg bw/day from the 90-day feeding study in dogs is considered the most appropriate study for use in the risk assessment. This NOAEL is based on calculi, haemorrhage, inflammatory changes and epithelial hyperplasia in the bladder at the LOAEL of 335 mg/kg bw/day. The target margin of exposure (MOE) of 100 includes a 10X uncertainty factor for interspecies extrapolation and a 10X uncertainty factor for intraspecies variability. No additional uncertainty factors were required. The selection of this study and MOE is considered to be protective of all populations including nursing infants and the unborn children of exposed female workers. An absorption factor of 50% was applied to the NOAEL to account for absorption in the GI tract; resulting in a NOAEL of 74.5 mg/kg bw/day for both dermal and inhalation exposure.

3.4.1.1 Dermal Absorption

A default dermal absorption value of 100% was used in the risk assessment.

3.4.2 Occupational Exposure and Risk

3.4.2.1 Mixer/Loader/Applicator Exposure and Risk Assessment

Individuals have potential for exposure to AE1162464 WG63 Herbicide or Velocity Herbicide during mixing, loading and application. Dermal and inhalation exposure estimates for workers applying AE1162464 WG63 Herbicide to corn and Velocity Herbicide to wheat were generated from PHED.

Exposure to workers mixing, loading and applying AE1162464 WG63 Herbicide or Velocity Herbicide is expected to be short-term in duration and to occur primarily by the dermal route. Exposure estimates were derived for mixer/loaders/applicators applying AE1162464 WG63 Herbicide to corn using groundboom application equipment and applying Velocity Herbicide to wheat using groundboom or aerial application equipment. The exposure estimates are based on mixers/loaders/applicators wearing long sleeves, long pants, shoes plus socks and chemical resistant gloves during mixing/loading, clean up and equipment repair.

Chemical-specific data for assessing human exposures during pesticide handling activities were not submitted.

Dermal exposure was estimated by coupling the unit exposure values with the amount of product handled per day and the dermal absorption value. Inhalation exposure was estimated by coupling the unit exposure values with the amount of product handled per day with 100% inhalation absorption. Exposure was normalized to mg/kg bw/day by using 70 kg adult body weight.

Exposure estimates were compared to the toxicological endpoints to obtain the margin of exposure (MOE); the target MOE is 100.

Exposure and Risk Estimates for Workers Mixing/Loading and Applying AE1162464 WG63 Herbicide to Corn

Scenario	Exposure (µg/kg bw/day)[a]		MOE[b]		
	Dermal	Inhalation	Dermal	Inhalation	Combined
Farmers	6.37	0.064	11 700	1 164 000	11 600
Custom Applicator	12.74	0.128	5848	582 000	5790

[a] Exposure Estimates= PHED Exposure (g ai/kg ai handled) x Rate x Volume handled ((L/day)
bw (70kg)

[b] MOE = NOAEL (74.5 mg/kg bw/d)
Exposure estimates (mg/kg/day)

Exposure and Risk Estimates for Workers Mixing/Loading and Applying Velocity Herbicide to Wheat

Scenario	Exposure (µg/kg bw/day)[a]		MOE[b]		
	Dermal	Inhalation	Dermal	Inhalation	Combined
Farmers, groundboom	0.90	0.027	82 800	2 760 000	80 400
Custom Applicator, groundboom	1.80	0.055	41 400	1 350 000	40 200
Aerial Mix/load	1.79	0.056	41 600	1 330 000	40 400
Aerial Applicator	0.338	0.0025	220 000	24 800 000	219 000

[a] Exposure Estimates= PHED Exposure (g ai/kg ai handled) x Rate x Volume handled (L/day)
bw (70kg)

[b] MOE = NOAEL (74.5 mg/kg bw/d)
Exposure estimates (mg/kg/day)

3.4.2.2 Exposure and Risk Assessment for Workers Entering Treated Area:

There is potential for exposure to workers re-entering areas treated with AE1162464 WG63 Herbicide or Velocity Herbicide. Given the early crop stage of application, the only contact with treated foliage is expected to occur during early season scouting in low crop heights (i.e. crops with minimal foliage). Given the nature of activities performed, dermal contact with treated surfaces should be minimal. The duration of exposure is considered to be short-term, and the primary route of exposure for workers re-entering treated areas would be through dermal contact with treated foliage.

Dermal exposure to workers entering treated areas is estimated by coupling dislodgeable foliar residue values with activity-specific transfer coefficients. The activity transfer coefficient for wheat is based on data from hoeing in cotton and beans. The activity transfer coefficient for corn is based on data from scouting in sweet corn. Chemical-specific dislodgeable foliar residue data were not submitted. As such, a default dislodgeable foliar residue value of 20% of the application rate was used in the exposure assessment.

Exposure estimates were compared to the toxicological end point to obtain the margin of exposure (MOE); the target MOE is 100.

Postapplication Margin of Exposure on Corn and Wheat

Activity	Exposure (mg/kg bw/day)[a]	Margin of Exposure[b]
Scouting in minimal foliage wheat	0.000114	654 000
Scouting in minimal foliage corn	0.00137	54 320

a Estimated as 20% application rate □ transfer coefficient (cm^2/hour) □ 8 hour/day worked □ 100% dermal absorption / 70 kg body weight

b NOAEL/ Exposure; target MOE is 100.

3.4.3 Residential Exposure and Risk Assessment

Since there are no residential uses, no residential exposure is expected.

3.4.4 Bystander Exposure and Risk

Bystander exposure should be negligible since the potential for drift is expected to be minimal. Application is limited to agricultural crops only when there is low risk of drift to areas of human habitation or activity such as houses, cottages, schools and recreational areas, taking into consideration wind speed, wind direction, temperature, application equipment and sprayer settings.

3.5 Food Residues Exposure Assessment

3.5.1 Residues in Plant and Animal Foodstuffs

The residue definition for risk assessment and enforcement in plant products is thiencarbazone-methyl. The residue definition for risk assessment of animal commodities is thiencarbazone-methyl, where the residue definition for enforcement is thiencarbazone-methyl and the metabolite BYH 18636-MMT (marker compound). Data gathering/enforcement analytical methods are valid for the quantification of thiencarbazone-methyl residues in/on corn and wheat, and residues of thiencarbazone-methyl and the metabolite BYH 18636-MMT in livestock matrices. The residues of thiencarbazone-methyl are stable when stored in a freezer at <-18°C for up to 365 days. Field trials were conducted at exaggerated rates for the purposes of investigating residues in processed commodities, however, due to a lack of residues in the raw agricultural commodities no further analysis was conducted. Anticipated residues in livestock matrices were calculated based on the maximum theoretical dietary burden. Based on these calculations, residues in animal matrices are expected to be less than the combined limit of quantitation (0.02 ppm). Supervised residue trials conducted throughout the United States and Canada using end-use products containing thiencarbazone-methyl at exaggerated rates is sufficient to support the proposed maximum residue limits for field corn and wheat (domestic) and sweet corn and popcorn (import).

3.5.2 Dietary Risk Assessment

A chronic dietary risk assessment was conducted using the Dietary Exposure Evaluation Model (DEEM-FCID™, Version 2.0), which uses updated food consumption data from the United States Department of Agriculture's Continuing Surveys of Food Intakes by Individuals, 1994-1996 and 1998.

3.5.2.1 Chronic Dietary Exposure Results and Characterization

A basic chronic dietary exposure assessment was performed taking into account maximum residue trial data from treated crops and animal matrices (meat, meat by-products and milk). The basic chronic dietary exposure from all supported thiencarbazone-methyl food uses ranges from 0.0% to 0.1% of the acceptable daily intake (ADI) for the total population, including infants and children.

Aggregate exposure to thiencarbazone-methyl from food and water is considered acceptable: 0.0% to 0.1% of the ADI for the total population. The highest aggregate exposure and risk estimate is for children (1 to 2 and 3 to 5 years old) at 0.1% of the ADI (see Appendix I, Table 6).

3.5.2.2 Acute Dietary Exposure Results and Characterization

No appropriate endpoint attributable to a single dose for the general population (including children and infants) was identified.

3.5.3 Maximum Residue Limits

Table 3.5.1 Proposed Maximum Residue Limits

Commodity	Recommended MRL (ppm)
Field corn, sweet corn kernel plus cob with husks removed*, popcorn grain*, wheat	0.01
Milk	0.02
Fat, meat, and meat by-products of cattle, goats, hogs, horses, poultry, sheep	0.02
Eggs	0.02

* MRLs on imported commodities

For additional information on Maximum Residue Limits (MRL) in terms of the international situation and trade implications, refer to Appendix II.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

The solubility of thiencarbazone-methyl is moderate at environmentally relevant pH values and exhibits a pH-dependence in water. Thiencarbazone-methyl is not expected to bioaccumulate in biota, as the log K_{OW} value is less than 1.0 at environmentally relevant pH values. The low vapour pressure and Henry's Law constant indicate that thiencarbazone-methyl is non-volatile in the environment. Therefore, thiencarbazone-methyl residues are not expected in the atmosphere, and long range atmospheric transport is not expected. Data related to the environmental fate of thiencarbazone-methyl and its major transformation are found in Appendix 1, Tables 7 and 8.

Thiencarbazone-methyl is slowly hydrolyzed under environmentally relevant conditions and is stable to photolysis in soil and water. Hydrolysis and phototransformation are not expected to be important routes of transformation in the environment.

Aerobic soil metabolism is an important route of transformation of thiencarbazone-methyl. Thiencarbazone-methyl is not expected to persist in aerobic soil environments but may persist in anaerobic soil conditions.

Anaerobic and aerobic aquatic metabolism are important routes of transformation of thiencarbazone-methyl. As thiencarbazone-methyl residues are non persistent in aquatic systems, prolonged exposure of aquatic organisms to thiencarbazone-methyl is unlikely under the proposed use pattern.

Thiencarbazone-methyl weakly sorbs to soil; however, the sorption behaviour correlates with soil organic matter. According to the soil mobility classifications of McCall et al.(1981) and Cohen et al. (1984) thiencarbazone-methyl is classified as moderately to highly mobile and may readily move into surface water through runoff and/or leach into ground water, depending on the permeability and organic matter content of the soil. Criteria for these classifications include: Koc of 0 - 50 (Koc of thiencarbazone-methyl is 46.4); solubility in water > 30 mg/L (thiencarbazone-methyl solubility in water is 436 mg/L at pH 7); Henry's Law Constant of $<10^{-2}$ atm-m^3/mol (Henry's Law Constant for thiencarbazone-methyl = 7.78E-14 atm-m^3/mol); negatively charged (either fully or partially) at ambient pH (Dissociation constant (pKa) of thiencarbazone-methyl = 3.0, either full or partial negative charge at pH 7); Hydrolysis half life >20 weeks (thiencarbazone-methyl hydrolysis half life 21 weeks); Photolysis half life > 1 week (thiencarbazone-methyl aqueous photolysis is 13 weeks, stable to photolysis in soil) Half life in soil > 2-3 weeks (thiencarbazone-methyl half life in aerobic soil in 36 days, thiencarbazone-methyl half life in anaerobic soil is 15 weeks).

Thiencarbazone-methyl was found at soil depths below 15 cm and in the Ontario field dissipation study was detected in the 45-60 cm soil depth.

Seven major transformation products were identified in environmental fate studies: BYH 18636-carboxylic acid, BYH 18636-sulfonamide-carboxylic acid, BYH 18636-sulfonamide, BYH 18636-MMT, BYH 18636-NMT, BYH18636-dicarboxy-sulfonamide and carbon dioxide. The major transformation products were identified in the hydrolysis, aerobic and anaerobic soil metabolism, aerobic and anaerobic aquatic metabolism and terrestrial field dissipation studies. Two minor transformation products BYH 18636-thieno-saccharine and BYH 18636-triazolinone-carboxamide were also identified in the photolysis and aerobic soil metabolism studies.

BYH18636-sulfonamide-carboxylic acid is expected to be persistent in the anaerobic aquatic environment although the potential for the formation and/or accumulation of BYH18636-sulfonamide-carboxylic acid in anaerobic systems is expected to be low. BYH18636-NMT was only detected in the anaerobic aquatic study and although classified as moderately persistent is not expected to accumulate in the environment. In terrestrial field dissipation studies major transformation products BYH 18636-carboxylic acid, BYH 18636-sulfonamide-carboxylic acid and BYH 18636-sulfonamide were detected at 45-60 cm soil depths and in mobility studies were determined to be just as or more mobile than thiencarbazone-methyl. BYH18636-carboxylic acid is considered non-persistent to moderately persistent in water and slightly to moderately persistent in sediment. BYH18636-MMT is moderately persistent in water.

Data on the fate and behaviour of thiencarbazone-methyl and its major transformation products are summarized in Appendix I Tables 7 and 8. The transformation pathway for thiencarbazone-methyl is summarized in Appendix I, Figure 1.

4.2 Effects on Non-Target Species

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental exposure concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (i.e., protection at the community, population or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (e.g., direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC). If the screening level risk quotient is below the level of concern (LOC), the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

4.2.1 Effects on Terrestrial Organisms

Effects of thiencarbazone-methyl on terrestrial organisms were based upon evaluation of toxicity data for three mammal and two bird species representing vertebrates (acute gavage, short- and long-term dietary exposure); one bee species, two other arthropods and one earthworm species representing invertebrates (acute or short-term exposure); and ten crop species representing plants (short-term exposure), see Appendix I, Table 9.

The toxicity of the major transformation products of thiencarbazone-methyl on the indicated terrestrial species was assessed as follows:

BYH18636-MMT was based upon evaluation of toxicity data for one collembolans species (long term exposure) and one earthworm species (long term exposure).

BYH18636-sulfonamide-carboxylic acid was based upon evaluation of toxicity data for one collembolans species (long term exposure) and one earthworm species (long term exposure).

BYH18636- carboxylic acid was based upon evaluation of toxicity data for one mammal species (short term), one collembolans species (long term exposure) and one earthworm species (short and long term exposure).

BYH18636- sulfonamide was based upon evaluation of toxicity data for one mammal species (short term), one collembolans species (long term exposure) and one earthworm species (long term exposure).

No effects are expected on terrestrial invertebrates, birds or mammals as risk quotients were less than 1 for all species tested when calculated using the highest application rate (7.5 g a.i./ha).

The EC_{25}s for terrestrial non-target plants were well below the application rates of 5.0 and 7.5 g a.i./ha, specifically, 0.468 g a.i./ha for ryegrass seedling emergence and 0.123 g a.i./ha for sunflower vegetative vigour. The 7 day exposure phase for the vegetative vigour test was followed by a 7 day recovery period i.e. 7 days without exposure to thiencarbazone-methyl. The plants at the two highest exposure levels continued to grow during the recovery phase but at study termination these plants were not considered normal or viable as compared to the control.

Based on the results from the toxicity studies done with the transformation products, no effects are expected on terrestrial invertebrates or mammals as toxicity endpoints were all less than the corresponding endpoints from the thiencarbazone-methyl studies. Based the results from acute and chronic toxicity studies done with earthworms and *Folsomia candida*, BYH18636-carboxylic acid, BYH18636-sulfonamide-carboxylic acid, BYH18636-sulfonamide, BYH18636-MMT and BYH18636-triazolinone-carboxamide were less toxic than thiencarbazone-methyl. Therefore, risk quotients for non-target terrestrial organisms were not calculated for any of these transformation products.

For spray drift, the screening level assumes 100% of the application drifts to non-target terrestrial plants. At the screening level assessment, if the risk exceeds the level of concern (i.e. RQ $\geq$1), then a Tier 1 assessment is triggered. Based on the screening level assessments, the level of concern was exceeded for non-target terrestrial plants.

A refined assessment was undertaken for plants in which the risks through spray drift were characterised (Appendix 1, Table 18). The off-target spray drift is approximately 6% of the application rate at the edge-of-field for field sprayers where the spray quality (droplet size distribution) is classified as ASAE medium. For aerial application, the edge-of-field spray drift is approximately 23% of the application rate. Based on the refined EECs calculated for drift from field boom sprayers, the level of concern was exceeded for non-target terrestrial plants which can be mitigated by buffer zones of 1 metre for ground application and buffer zones of 30 metres for aerial application.

All the data related to the toxicity of thiencarbazone-methyl and its major transformation products to terrestrial non-target organisms are presented in Appendix 1, Table 9. Screening level risk quotients calculated under a realistic worst-case scenario are presented in Appendix 1, Table 11.

4.2.2 Effects on Aquatic Organisms

Effects of thiencarbazone-methyl on aquatic organisms was based upon evaluation of toxicity data for two saltwater species (short and long term) representing marine invertebrates, one marine algae species (short term), three fish species (short and long-term), three freshwater algae species (short term), five aquatic plant species (short and long term), and two freshwater aquatic invertebrate species (short and long term), see Appendix I, Table 10.

The toxicity of thiencarbazone-methyl and its major transformation products on the indicated aquatic species was assessed as follows:

BYH18636-sulfonamide on aquatic organisms was based upon evaluation of toxicity data for one fish species (short term), one freshwater algae species (short term), one aquatic plant species (short term), and one freshwater aquatic invertebrate species (short term).

BYH18636-sulfonamide-carboxylic acid on aquatic organisms was based upon evaluation of toxicity data for one freshwater aquatic invertebrate species (short term).

BYH18636-carboxylic acid on aquatic organisms was based upon evaluation of toxicity data for one aquatic plant species (short term), and one freshwater aquatic invertebrate species (short term).

BYH18636-dicarboxy-sulfonamide and BYH18636-MMT on aquatic organisms was based upon evaluation of toxicity data for one aquatic plant species (short term).

In the freshwater environment, thiencarbazone-methyl has no risk of acute effects to fish or aquatic invertebrates. Thiencarbazone-methyl exhibited acute toxic effects to aquatic vascular plants with LC_{50}s ranging from 0.00053 mg a.i./L (*P. pectinatus*) to 0.00099 mg a.i./L (*L. gibba*) and to algae at concentrations ranging from 0.170 mg a.i./L (*P. subcapitata*) to 59.3 mg a.i./L (*N. pelliculosa*). The screening level risk quotients for aquatic vascular plants exceeded the level of concern (Appendix I, Table 16). Based on acute toxicity studies done with *Lemna gibba*, BYH18636-carboxylic acid, BYH18636-sulfonamide-carboxylic acid, BYH18636-sulfonamide, BYH18636-MMT and BYH18636-dicarboxyl-sulfonamide were less toxic than thiencarbazone-methyl. Therefore, risk quotients were not calculated for any of these transformation products.

In the marine environment, thiencarbazone-methyl poses no acute risk to fish, aquatic invertebrates or algae.

To assess the risk to amphibians for acute and chronic exposure, the toxicity values for the most sensitive fish species were used as surrogate data along with the EEC in a 15 cm deep body of water. The screening level risk quotients did not exceed the level of concern for amphibians, see Appendix I, Table 16.

Based upon screening level risk quotients, thiencarbazone-methyl does not pose a risk of chronic effects to freshwater aquatic invertebrates or marine/estuarine fish and mollusks. Additionally, thiencarbazone-methyl does not persist in aquatic systems, and as such, chronic exposure is not expected to occur, see Appendix I, Table 16.

For spray drift, the screening level assumes 100% of the application drifts to aquatic plants and algae. At the screening level assessment, if the risk exceeds the level of concern (i.e. RQ $\geq$1), then a Tier 1 assessment is triggered. Based on the screening level assessment, the level of concern was exceeded for non-target terrestrial plants.

A refined assessment was undertaken for plants in which the risks through spray drift were characterised see Appendix I, Table 18. The off-target spray drift is approximately 6% of the application rate at the edge-of-field for field sprayers where the spray quality (droplet size distribution) is classified as ASAE medium.

Based on the refined EECs calculated for drift from field boom sprayers see Appendix I, Table 18, the level of concern was exceeded for aquatic plants but not for algae. Based on the risk identified to aquatic plants, buffer zones of 1 metre for ground application are required. Further spray drift modelling indicated that buffer zones larger than 1 metre were not required.

Similarly, a refined exposure assessment is conducted which considers the off-target spray drift if thiencarbazone-methyl is applied by aircraft up to the edge of the treated field. For aerial application to crops, the off-target spray drift is approximately 23% of the application rate at the edge-of-field for a spray quality (droplet size distribution) classified as ASAE medium. This spray drift value was derived from the simulations of the AGDISP Model used for aerial application scenarios. The EEC based on spray drift from aircraft is outlined in see Appendix I, Table 18.

Based on the refined EECs calculated for drift from aerial application see Appendix I, Table 18.the level of concern was exceeded for aquatic and terrestrial plants. Based on the risk identified to aquatic plants, aquatic buffer zones of 1 metre will be required for freshwater habitat at depths of <1 metre. No marine habitat buffer zones are required.

5.0 Value

5.1 Effectiveness Against Pests

5.1.1 Acceptable Efficacy Claims for Velocity Herbicide

Efficacy data were submitted from at least 85 replicated field trials conducted in 2006 at several locations in Alberta, Saskatchewan and Manitoba. Treatments were included at various rates to determine the lowest effective rate. The herbicide treatments were applied using small plot application equipment, and were within the growth stage range indicated on the label.

The efficacy of Velocity Herbicide was visually assessed as percent weed control and compared to an untreated weedy check. Observations were made up to four times throughout the growing season. The data support the weed control claims summarized below.

Weed Control Claims for Velocity Herbicide

Herbicide Rate	Weeds Controlled	Weeds Suppressed
5 g a.i./ha or 0.5 L product/ha	Wild oats, green foxtail, barnyard grass, wild mustard, redroot pigweed, stinkweed, shepherd's purse, hemp-nettle, volunteer canola*, cleavers, pale smartweed, wild buckwheat,	Yellow foxtail, Persian darnel, lamb's quarters, Russian thistle

* non-ALS tolerant

5.1.2 Acceptable Efficacy Claims for AE1162464 WG63 Herbicide

Efficacy data were submitted from at least 17 replicated field trials conducted between 2005 and 2007 at several locations including Ontario and the United States. Treatments included at various rates to determine the lowest effective rate. The herbicide treatments were applied using small plot application equipment, and were within the growth stage range indicated on the label.

The efficacy of AE1162464 WG63 Herbicide was visually assessed as percent weed control and compared to an untreated weedy check. Observations were made up to four times throughout the growing season. The data support the weed control claims summarized below.

Weed Control Claims for AE1162464 WG63 Herbicide

Herbicide Rate	Weeds Controlled	Weeds Suppressed
7.5 g a.i./ha (72 g product/ha) + 0.25% v/v Agral 90 + 2.5 L/ha 28% UAN	Redroot pigweed, green foxtail	Lamb's quarters

5.1.3 Herbicide Tank Mix Combinations

5.1.3.1 Velocity Herbicide

Data from at least 100 trials conducted in 2006 at multiple locations in Alberta, Saskatchewan and Manitoba, were submitted in support of the proposed tank mixes. Some trials included multiple crops, and many trials included treatments of Velocity Herbicide applied at the 2X rate.

The efficacy of Velocity Herbicide was visually assessed as percent weed control and compared to an untreated weedy check. Observations were made up to four times throughout the growing season. The data support the tank mixtures with Velocity Herbicide for use in spring wheat and durum wheat summarized below.

Acceptable Tank Mixtures for Velocity Herbicide

Tank Mix Partner	Rate
For Use in Spring Wheat	
MCPA Ester	up to 350 g ae/ha
2,4-D Ester	up to 350 g ae/ha
Buctril M	1.0 L/ha (560 g ae/ha)
Thumper	1.0 L/ha (560 g ae/ha)
Infinity Herbicide	0.83 L/ha (205 g ai/ha)
Attain Herbicide Tank Mix	0.6 L/ha Attain A + 1.0 L/ha Attain B (108 + 564 g ai/ha)
Curtail M	1.5 L/ha (495 g ae/ha)
Refine SG	30 g/ha (15 g ai/ha)
Refine SG + MCPA Ester	30 g/ha (15 g ai/ha) + up to 350 g ae/ha
Refine SG + 2,4-D Ester	30 g/ha (15 g ai/ha) + up to 350 g ae/ha
Refine DF	20 g/ha (15 g ai/ha)
Refine DF + MCPA Ester	20 g/ha (15 g ai/ha) + up to 350 g ae/ha
Refine DF + 2,4-D Ester	20 g/ha (15 g ai/ha)+ up to 350 g ae/ha
Frontline Herbicide Tank Mix	0.1 L/ha (5 g ai/ha) Frontline A + 0.7 L/ha (350 g ai/ha) Frontline B
For Use in Durum Wheat	
MCPA Ester	up to 350 g ae/ha
2,4-D Ester	up to 350 g ae/ha
Infinity Herbicide	0.83 L/ha (205 g ai/ha)

5.1.3.2 AE1162464 WG63 Herbicide

No tank mixtures with AE1162464 WG63 Herbicide were proposed.

5.1.4 Rainfastness

The data from three simulated rainfall trials, using overhead irrigation, were submitted in support of a one hour rainfast interval. Treatments of Velocity Herbicide were applied at 30, 60, 120 and 240 minutes prior to a simulated rainfall event of 25 mm of water across the entire trial area. Efficacy was visually assessed up to three times during the growing season, and was reported as percent control on a weed species-specific basis.

5.1.4.1 Supported Rainfastness Claim

The efficacy of Velocity Herbicide was similar four hours after application and one hour after application. The data support a rainfastness claim of one hour for Velocity Herbicide. The same rainfastness claim is also acceptable for AE1162464 WG63 Herbicide.

5.1.5 Water Volumes Including Aerial Application

The data from ground and simulated aerial application (low water volume) trials were submitted in support of a minimum spray volume of 28.1 L/ha (air) and 46.8 L/ha (ground and air) for Velocity Herbicide and 150 L/ha (ground) for AE1162464 WG63 Herbicide. Herbicide treatments of Velocity Herbicide were made in 28.1 or 46.8 L/ha of water and compared to treatments made in higher water volumes. All applications were made using ground boom equipment. In addition, the trials included treatments applied in 28.1 L of water per ha to demonstrate the weed control provided by a relevant registered commercial herbicide that is labelled for aerial application.

The data support the application of Velocity Herbicide in a minimum water volume of 28.1 L/ha for application with aerial equipment and 46.8 L/ha for application with ground equipment.

The data support the application of AE1162464 WG63 Herbicide in a minimum water volume of 150 L/ha for application with ground equipment.

5.2 Phytotoxicity to Host Plants

5.2.1 Velocity Herbicide

Data from at least 100 trials conducted in 2006 at multiple locations in Alberta, Saskatchewan, and Manitoba, were submitted in support of the host crop tolerance claims. Some trials included multiple crops, and all trials included treatments of Velocity Herbicide applied at the 2X rate.

Crop injury (%) was visually assessed up to three times during the growing season, and many trials reported crop yield, expressed as a percentage of a weed-free check.
Crop injury to spring and durum wheat was acceptable.

5.2.2 AE1162464 WG63 Herbicide

Data from 10 trials conducted at multiple locations in 2005 and 2006 in Ontario and Québec were submitted in support of the host crop tolerance claims. The trials included treatments of AE1162464 WG63 Herbicide applied at the 2X rate.

Crop injury (%) was visually assessed up to three times during the growing season, and many trials reported crop yield, expressed as a percentage of a weed-free check.

Crop injury to field corn was acceptable.

5.3 Impact on Succeeding Crops

Rotational crop tolerance data were submitted from 29 trials that were initiated within one year following an application of thiencarbazone-methyl. The number of trials in which tolerance was evaluated varied by rotational crop. Trials were conducted in Alberta, Saskatchewan, Manitoba, and Ontario.

5.3.1 Acceptable Claims for Rotational Crops for Thiencarbazone-methyl

The crop injury and yield data support a rotational crop tolerance claim for the following crops planted in the year (10 months) after application of thiencarbazone-methyl: alfalfa, barley, canaryseed, canola, field corn, dry beans (all market classes), field pea, flax, mustard, soybean, tame oats, and wheat (spring, winter and durum). The following crops can be accepted conditionally, pending the submission and review of additional data: chickpea, lentil and timothy.

5.4 Economics

Wheat is Canada's most important field crop, individually out-producing all other cereal, pulse, oilseed and hay crops. In 2006, wheat was grown on nearly 10.7 million hectares and produced about 27.3 million tonnes of grain. The majority of spring and durum wheat is grown in Western Canada. From 2002 to 2006, Manitoba, Saskatchewan and Alberta produced approximately 90% of the total wheat in Canada. More specifically, the three provinces together produced on average 97% and 100% of Canada's spring wheat and durum wheat, respectively. Wheat is Canada's largest Agri-food export. Export volumes of wheat in the 2001 to 2005 crop years averaged almost 15 million tonnes annually. In 2003 and 2004, Canada exported $2.826 and $3.479 billion (CDN), respectively. These wheat exports accounted for 11% and 13% of the total Canadian agri-food exports, respectively.

Corn is the most important grain crop of Ontario and Quebec, individually out-producing all cereal, pulse, oilseed or hay crops in the past crop year. In 2006, grain corn was grown on over one million hectares in Canada and produced about 9 million tonnes of grain with the majority of that production occurring in Ontario and Quebec. Across Canada, corn ranks as the 5th largest crop contributing to field crop receipts, providing growers with a significant portion of their farming income.

5.5 Sustainability

5.5.1 Survey of Alternatives

5.5.1.1 Alternatives to Velocity Herbicide

In Canada, several post-emergent herbicides are registered for broadleaf weed control in spring and durum wheat. These herbicides have various modes of action including Groups 2 (ALS/AHAS inhibitors), 4 (growth regulator herbicides), 5 (photosynthetic inhibitors - triazines), 6 (photosynthetic inhibitors - nitriles/benzothiadiazoles), and 7 (photosynthetic inhibitors - ureas/amides). Several grassy weed herbicides are also available to western Canadian growers. These herbicides have various modes of action including Groups 1 (ACCase inhibitors such as clodinofop-propargyl, diclofopmethyl, fenoxaprop-p-ethyl, pinoxaden, and tralkoxydim), 2 (ALS/AHAS inhibitors such as flucarbazone-sodium, imazamox, imazamethabenz, and sulfosulfuron), 3 (mitotic inhibitors such as trifluralin) and 8 (unknown modes of action such as difenzoquat, and triallate).

5.5.1.2 Alternatives to AE1162464 WG63 Herbicide

In Canada, several post-emergent herbicides are registered for grassy and broadleaf weed control in corn. These herbicides have various modes of action including Groups 2 (ALS/AHAS inhibitors), 4 (growth regulator herbicides), 5 (photosynthetic inhibitors - triazines), 6 (photosynthetic inhibitors - nitriles / benzothiadiazoles), 7 (photosynthetic inhibitors - ureas/amides), 8 (Inhibition of lipid synthesis, but not ACCase inhibition - thiocarbamates), 9 (Inhibition of EPSP synthase - glyphosate), 10 (Inhibition of glutamine synthetase - glufosinate ammonium), 15 (Inhibition of cell division, Inhibition of VLCFAs - chloroacetamides), 19 (Inhibition of auxin transport - semicarbazones), and 27 (bleachers, or inhibitors of 4-hydroxyphenyl-pyruvatedioxygenase - triketones).

5.5.2 Compatibility with Current Management Practices Including Integrated Pest Management

5.5.2.1 Velocity Herbicide

Velocity Herbicide provides a new option for controlling broadleaf weeds in spring and durum wheat. Unlike other grassy weed herbicides available to growers, Velocity Herbicide controls a range of both grassy and broadleaved weeds in a single pass. Velocity Herbicide is the only Group 2 herbicide that controls wild oat, green foxtail and barnyard grass. Velocity Herbicide can be combined in tank-mixture with a number of broadleaf herbicides to control additional

weeds not listed on the Velocity Herbicide label. Spring and durum wheat have demonstrated tolerance to Velocity Herbicide. In addition it has a more favourable rotational crop profile than the leading Group 2 commercial standard. The use of Velocity Herbicide does not restrict the sequential use of other chemicals of alternate modes of action.

5.5.2.2 AE1162464 WG63 Herbicide

AE1162464 WG63 Herbicide provides an additional Group 2 herbicide option for post-emergent control of selected grassy and broadleaf weeds. AE1162464 WG63 Herbicide is compatible with current weed management practices including IPM. The use of AE1162464 WG63 Herbicide does not restrict the sequential use of other chemicals of alternate modes of action for control of weeds not controlled by the product alone. Crop rotation is an important IPM practice and after an application of AE1162464 WG63 Herbicide in corn, important rotational crops in eastern Canada, such as winter wheat and soybean, can be planted.

5.5.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Resistance to ALS inhibiting herbicides is widespread, with 16 weed species having documented resistance to date in Canada, and 95 species worldwide (http://www.weedscience.org/In.asp).

Repeated use of herbicides having the same mode of action in a weed control program increases the probability of selecting naturally resistant biotypes. Therefore, thiencarbazone-methyl should be used in rotation with herbicides having different modes of action.

Both the Velocity Herbicide label and the AE1162464 WG63 Herbicide label include the resistance management statements, as per Regulatory Directive DIR99-06, *Voluntary Pesticide Resistance-Management Labeling Based on Target Site/Mode of Action.*

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the federal government's Toxic Substances Management Policy, which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

During the review process, thiencarbazone-methyl was assessed in accordance with the PMRA Regulatory Directive DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy. Substances associated with the use of thiencarbazone-methyl were also considered, including transformation products formed in the environment, and contaminants and formulants in the technical product and the end-use products. Thiencarbazone-methyl and its transformation products were evaluated against the following Track 1 criteria: persistence in soil ≥182 days; persistence in water ≥182 days; persistence in sediment ≥365 days; persistence in air ≥2 days; bioaccumulation log K_{ow} ≥5 or BCF ≥5000 (or BAF ≥5000). In order for thiencarbazone-methyl or its transformation products to meet Track 1 criteria, the criteria for both bioaccumulation and persistence (in one media) must be met. The technical product and end-use products, including formulants, were assessed against the contaminants identified in the Canada Gazette, Part II, Volume 139, Number 24, pages 2641-2643: List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern, Part 3 Contaminants of Health or Environmental Concern. The PMRA has reached the following conclusions:

Thiencarbazone-methyl does not meet the Track 1 criterion for persistence in air because volatilisation is not an important route of dissipation and long-range atmospheric transport is unlikely to occur based on its vapour pressure (8.8 x 10-14 Pa @ 20°C) and Henry's Law constant (7.88 x 10-14 pascal*m^3/mole at pH 7; 20°C). Thiencarbazone-methyl does not meet the Track 1 criterion for bioaccumulation, as its octanol-water partition coefficient (log K_{ow} - 1.98 at pH 7) is below the Track 1 criterion. Thiencarbazone-methyl does not meet the Track 1 criterion for persistence in soil or water because its persistence in soil is < 182 days and its persistence in water is also < 182 days. Therefore, thiencarbazone-methyl does not meet the Track 1 criteria for persistence in air, water or soil.

Thiencarbazone-methyl does not form any transformation products that meet the Track 1 criteria.

There are no Track 1 formulants in the technical product or end-use products.

There are no Track 1 contaminants in the technical product or end-use products.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, formulants and contaminants in the technical and end-use products are assessed against the formulants and contaminants identified in the Canada Gazette, Part II, Volume 139, Number 24, pages 2641-2643: List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern. This list of formulants and contaminants of health and environmental concern are identified using existing policies and regulations including: the federal Toxic Substances Management Policy; the Ozone-depleting Substance Regulations, 1998, of the Canadian Environmental Protection Act (substances designated under the Montreal Protocol); and the PMRA Formulants Policy as described in the PMRA Regulatory Directive DIR2006-02, Formulants Policy and Implementation Guidance Document. The List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern is maintained and used as described in the PMRA Notice of Intent NOI2005-01, List of Pest

Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.

The List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern consists of three parts:
Part 1: Formulants of Health or Environmental Concern;
Part 2: Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions; and
Part 3: Contaminants of Health or Environmental Concern.

The contaminants to which Part 3 applies meet the federal Toxic Substances Management Policy criteria as Track 1 substances, and are considered in section 6.1. The following assessment refers to the formulants and contaminants in Part 1 and Part 2 of the list.

Technical grade thiencarbazone-methyl and the end-use product AE1162464 WG63 Herbicide do not contain any formulants or contaminants of health or environmental concern identified in the Canada Gazette, Part II, Volume 139, Number 24, pages 2641-2643: List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern. However, the end-use product, Velocity Herbicide, does contain an aromatic petroleum distillate. Therefore, the label for the end-use product Velocity Herbicide will include the statement: "This product contains an active ingredient and aromatic petroleum distillates which are toxic to aquatic organisms and non-target terrestrial plants."

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for thiencarbazone-methyl is adequate to define the majority of toxic effects that may result from exposure to thiencarbazone-methyl. In subchronic and chronic studies on laboratory animals, the primary target was the bladder and kidney. Although there was no evidence of carcinogenicity in rats after longer-term dosing, there was evidence of cancer in the urinary bladders of mice but only at doses where distinct precursor urinary tract changes were previously noted. Although these tumours were considered to be of limited relevance to humans, they are taken into account in the risk assessment. There was no evidence of increased susceptibility of the young in reproduction or developmental toxicity studies, and thiencarbazone-methyl was not considered to be a neurotoxicant. The risk assessment protects against the toxic effects noted above by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

The nature of the residue in cereals and animals is adequately understood. The residue definition for enforcement is thiencarbazone-methyl for cereals and thiencarbazone-methyl plus the metabolite BYH 18636-MMT in foods of animal origin. The proposed use of thiencarbazone-methyl on corn (field, pop and sweet) and wheat does not constitute an unacceptable chronic dietary risk (food and drinking water) to any segment of the population, including infants, children, adults and seniors. Sufficient crop residue data have been reviewed to recommend maximum residue limits to protect human health.

Mixer, loader applicators handling AE1162464 WG63 Herbicide or Velocity Herbicide and workers re-entering corn fields treated with AE1162464 WG63 Herbicide or wheat fields treated with Velocity Herbicide are not expected to be exposed to levels of thiencarbazone-methyl that will result in an unacceptable risk when the AE1162464 WG63 Herbicide and Velocity Herbicide are used according to label directions. The personal protective equipment on the product labels are adequate to protect workers.

7.2 Environmental Risk

The solubility of thiencarbazone-methyl is moderate at environmentally relevant pH values and exhibits a pH-dependence in water. Thiencarbazone-methyl is not expected to bioaccumulate in aquatic organisms, as the log K_{OW} value is less than 1.0 at environmentally relevant pH values.

Thiencarbazone-methyl is not expected to persist in aerobic soil environments but may persist under anaerobic soil conditions. Thiencarbazone-methyl is slightly persistent in aerobic aquatic environments but is not expected to persist under anaerobic aquatic conditions. Aerobic soil metabolism and anaerobic aquatic metabolism are the primary routes of transformation of thiencarbazone-methyl in the environment. As thiencarbazone-methyl residues are non persistent in aquatic systems, prolonged exposure of aquatic organisms to thiencarbazone-methyl is unlikely under the proposed use pattern.

Hydrolysis and phototransformation are not expected to be important routes of transformation in the environment.

Thiencarbazone-methyl weakly sorbs to soil and its adsorption positively correlates with soil organic matter. Thiencarbazone-methyl is moderately to highly mobile and may readily move into surface water through runoff and/or leach into ground water, depending on the permeability and organic matter content of the soil.

Seven major transformation products were identified in the hydrolysis, aerobic and anaerobic soil metabolism, aerobic and anaerobic aquatic metabolism and terrestrial field dissipation studies.

Risk Characterization
Risk quotients were calculated using the highest proposed rate of 7.5 g a.i./ha.

Terrestrial organisms: No effects are expected on terrestrial invertebrates, birds or mammals. Risk quotients (EEC/toxicity endpoints) were less than 1 for all species tested.

Non-target terrestrial plants: Risk quotients exceed the level of concern for terrestrial non-target plants.

Aquatic organisms: No effects are expected on aquatic invertebrates, fish, mollusks, freshwater algae or crustaceans as risk quotients were less than 1.

Aquatic plants: Risk quotients exceed the level of concern for aquatic vascular plants.

Based on the risk identified to off-target sensitive habitats, buffer zones are required to protect freshwater and terrestrial habitats - see Environmental Label Statements for Velocity Herbicide and AE1162464 WG63 Herbicide Labels under Measures to Minimize Risk.

7.3 Value

7.3.1 Velocity Herbicide

The value data submitted in support of Velocity Herbicide are adequate to describe its efficacy for use in spring and durum wheat. A single post-emergence application of Velocity Herbicide provides control of many weeds in spring and durum wheat, including wild oats, barnyard grass and green foxtail. The submitted phytotoxicity and yield data demonstrate an adequate margin of safety of labeled crops to Velocity Herbicide. Velocity Herbicide also has a flexible re-cropping profile.

7.3.2 AE1162464 WG63 Herbicide

The value data submitted in support of AE1162464 WG63 Herbicide are adequate to describe its efficacy for use in field corn. A single post-emergence application of AE1162464 WG63 Herbicide provides control of redroot pigweed and green foxtail, and suppression of lamb's quarters, in field corn. The submitted phytotoxicity and yield data demonstrate an adequate margin of safety of labeled host crops to AE1162464 WG63 Herbicide.

8.0 Regulatory Decision

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, has granted conditional registration for the sale and use of Thiencarbazone-methyl Technical Herbicide, Velocity Herbicide and AE1162464 WG63 Herbicide, containing the technical grade active ingredient thiencarbazone, to control specific weeds in corn and wheat.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

Although the risks and value have been found acceptable when all risk reduction measures are followed, the applicant must submit additional scientific information as a condition of registration. For more details, refer to the Section 12 Notice associated with these conditional registrations. The applicant must submit the following information by September 30, 2010.

NOTE: The PMRA will publish a consultation document at the time when there is a proposed decision on applications to convert these conditional registrations to full registrations or on applications to renew the conditional registrations, whichever occurs first.

Human Health
Final storage stability report (18 months)

Sample extraction and analysis dates for all samples from the wheat CFT to ensure that the analysis was completed within the period of demonstrated freezer stability.

Value
Tank mixes: an additional three trials are required for the tank mix of Velocity + Refine DF + 2,4-D ester in spring wheat without Agral 90. At least two trials should be taken to yield. An additional three trials are required for each of the tank mixes in durum wheat (Velocity + 2,4-D ester, Velocity + MCPA ester, and Velocity + Infinity). At least two trials for each tank mix should be taken to yield.

Rotational crops: an additional two trials in chickpea are required, with at least one taken to yield. An additional four trials in lentils are required, with at least two taken to yield. An additional three trials in timothy are required, with at least one taken to yield.

List of Abbreviations

µg	micrograms
A	acres
AD	adminstered dose
ae	acid equivalent
ADI	acceptable daily intake
a.i.	active ingredient
ALS	acetolactate synthase
ARfD	acute reference dose
BAF	bioaccumulation factor
BCF	bioconcentration factor
bw	body weight
cm	centimetres
dw	dry weight
DT_{50}	dissipation time 50% (the dose required to observe a 50% decline in the test population)
EC_{25}	effective concentration on 25% of the population
EC_{50}	effective concentration on 50% of the population
EEC	estimated environmental concentration
ER_{25}	effective rate for 25% of the population
FDA	Food and Drugs Act
g	gram
GAP	good agricultural practices
ha	hectare(s)
HPLC	high performance liquid chromatography
kg	kilogram
K_{oc}	organic-carbon partition coefficient
K_{ow}	*n*–octanol-water partition coefficient
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOAEL	lowest observed adverse effect level
LOC	level of concern
LOEC	low observed effect concentration
LOQ	limit of quantitation
LR_{50}	lethal rate 50%
m	metre
MAS	maximum average score
mg	milligram
MIS	maximum irritation score
mL	millilitre
mm	millimetre
MOA	mode of action
MOE	margin of exposure
MRL	maximum residue limit
MS	mass spectrometry

MTD	maximum tolerated dose
MTDB	maximum theoretical dietary burden
N/A	not applicable
NAFTA	North American Free Trade Agreement
nm	nanometres
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NOER	no observed effect rate
Pa	pascals
PBI	plantback interval
PHED	Pesticide Handlers Exposure Database
PHI	preharvest interval
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
ppm	parts per million
RQ	risk quotient
SF	safety factor
$t_{1/2}$	half-life
TRR	total radioactive residue
TSMP	Toxic Substances Management Policy
UAN	urea ammonium nitrate
UF	uncertainty factor
US	United States
UV	ultraviolet
v/v	volume per volume dilution
WSSA	Weed Science Society of America

Appendix I Tables and Figures

Table 1 Residue Analysis

Matrix	Method ID	Analyte	Method Type	LOQ	Reference
Plant	00963	Thiencarbazone-methyl BYH 18636-N-desmethyl BYH 18636-MMT-glu(y)coside	HPLC-MS/MS (enforcement/data gathering)	0.01/analyte	1410014
	00962	Thiencarbazone-methyl BYH 18636-N-desmethyl BYH 18636-MMT-glu(y)coside Cyprosulfamide	HPLC-MS/MS (data gathering)	0.01/analyte	1410006
Animal	01022	Thiencarbazone-methyl BYH 18636-MMT	HPLC-MS/MS (enforcement/data gathering)	0.01/analyte	1410005
	00990	Thiencarbazone-methyl BYH 18636-MMT BYH 18636-sulfonamide BYH 18636-methyl carbamate	HPLC-MS/MS (data gathering)	0.01/analyte	1410003
Soil	01028	BYH18636[1]	HPLC-MS/MS m/z 389-128	1 µg/kg	1410017
Soil and Sediment	GS-003-S06-02		HPLC-MS/MS	LOQ (ng/g)	1410018 and 1410015
			m/z	Soil Sediment	
		BYH18636	391-359	0.4 0.3	
		BYH18636-MMT	130-115	1.0 0.7	
		BYH18636-triazolinone carboxamide	173-130	0.9 0.4	
		BYH18636-sulfonamide carboxylic acid	220-176	0.6 0.4	
		BYH18636-sulfonamide	236-204	1.0 1.3	
		BYH18636-carboxylic acid	375-202	0.4 0.2	
Water	01025	BYH18636	HPLC-MS/MS m/z 389-128	0.05µg/L	1410022

Matrix	Method ID	Analyte	Method Type	LOQ	Reference
Water	GS-004-W06-02	BYH18636 BYH18636-dicarboxy sulfonamide BYH18636-MMT BYH18636-sulfonamide carboxylic acid BYH18636-sulfonamide BYH18636-carboxylic acid	HPLC-MS/MS m/z 391-359 250-162 130-115 220-176 236-204 375-202	LOQ of the method is 0.5 ng/mL for the parent compound and all metabolites	1410020 and 1410021
[1] Thiencarbazone-methyl (parent compound)					

Table 2 Acute Toxicity of Thiencarbazone-methyl and Its Associated End-use Products

Study Type	Species	Result	Comment	Reference
Acute Toxicity of Thiencarbazone-methyl (Technical)				
Oral (Acute Toxic Class Method)	Rats	LD_{50} > 2000 mg/kg bw	Low Toxicity	1410037
Oral (Acute Toxic Class Method)	Rats	LD_{50} > 2000 mg/kg bw	Low Toxicity	1410036
Dermal	Rats	LD_{50} > 2000 mg/kg bw	Low Toxicity	1410038
Inhalation	Rat	LC_{50} > 5.158 mg/L	Low Toxicity	1410039
Skin Irritation	Rabbits	MAS = 0	Non-irritating	1410040
Eye Irritation	Rabbits	MAS = 0.67 MIS = 4.6	Minimally irritating	1410041
Skin Sensitization (Maximization)	Guinea Pigs	Negative	Not a dermal sensitizer	1410042
Acute Toxicity of End-Use Product – AE1162464 WG63 HERBICIDE				
Oral (Up & Down)	Rats	LD_{50} > 2000 mg/kg bw	Low Toxicity	1408955
Dermal	Rat	LD_{50} > 2000 mg/kg bw	Low Toxicity	1408956
Inhalation	Rat	LC_{50} > 2.05 mg/L	Low Toxicity	1408957
Skin Irritation	Rabbit	MAS = 0.87	Non-irritating	1408958

Study Type	Species	Result	Comment	Reference
Eye Irritation	Rabbit	MAS = 25.9 MIS = 32.3	Moderately irritating	1408959
Skin Sensitization (Buehler Method)	Guinea Pigs	Negative	Not a dermal sensitizer	1408960
Acute Toxicity of End-Use Product - [SP102000015037 SC547 HERBICIDE				
Oral (Up & Down)	Rats	LD_{50} > 2000 mg/kg bw	Low Toxicity	1408760
Dermal	Rat	LD_{50} > 2000 mg/kg bw	Low Toxicity	1408761
Inhalation	Rat	LC_{50} > 2.04 mg/L	Low Toxicity	1408762
Skin Irritation	Rabbit	MAS = 0.6	Slightly irritating	1408763
Eye Irritation	Rabbit	MAS = 3.8 MIS = 24	Mildly irritating	1408764
Skin Sensitization (Buehler Method)	Guinea Pigs	Negative	Not a dermal sensitizer	1408765
Acute Toxicity of End-Use Product - VELOCITY HERBICIDE				
Oral (Acute Toxic Class Method)	Rat	LD_{50} > 2000 mg/kg bw	Low Toxicity	1408878
Dermal	Rats	LD_{50} > 2000 mg/kg bw	Low Toxicity	1408879
Inhalation	Rats	LC_{50} > 1.728 mg/L	Slight Toxicity	1408880
Skin Irritation	Rabbits	MAS = 2.9	Mildly irritating	1408882
Eye Irritation	Rabbit	MAS = 37.7 MIS = 43	Moderately irritating	1408883
Skin Sensitization (LLNA)	Mouse	SI = 0.85-2.2	Not a dermal sensitizer	1408884

a MAS = maximum average score for 24, 28 and 72 hours

b MIS = maximum irritation score

Table 3 Toxicity Profile of Technical Thiencarbazone-methyl

Study Type	Species	Results[a] (mg/kg/day in M/F)	Reference
21-day dermal	Waiver requested and granted based on low toxicity and dermal absorption.		
90-day dietary	Mouse	NOAEL: 315 mg/kg bw/day (♂); 789 mg/kg bw/day (♀) LOAEL: 637 mg/kg bw/day (♂), based on urinary bladder calculi accompanied by marked, submucosal inflammatory cell infiltration, minimal, diffuse urothelial inflammation and moderate, diffuse urothelial hyperplasia of the urinary bladder. LOAEL: Not established. (♀)	1410043
90-day dietary with minimal neurotoxicity tested (limited FOB and motor activity)	Rat	NOAEL: 123/154 mg/kg bw/day (♂/♀) LOAEL: 439/543 mg/kg bw/day (♂/♀), based on increased ALP (not present at end of recovery) urinary bladder had gritty content (with stones) (not present at end of recovery), intrapelvic eosinophilic urolithiasis in the kidneys , eosinophilic urolithiasis within the lumen of the urinary bladder (not present at end of recovery), simple diffuse urothelial hyperplasia and collecting duct hyperplasia.	1410044
90-day dietary	Dog	NOAEL: 149/159 mg/kg bw/day (♂/♀) LOAEL: 335/351 mg/kg bw/day (♂/♀), based on calculi, haemorrhage, inflammatory changes and epithelial hyperplasia in the bladder.	1410045
12-month dietary	Dog	NOAEL: 117 mg/kg bw/day (♂); 200 mg/kg bw/day (♀) LOAEL: 179 mg/kg bw/day (♂), based on increased mean urinary protein, calculi, abnormal consistency, transitional cell hyperplasia, slight congestion, slight haemorrhage, slight inflammation, minimal calculi and moderate ulceration in the bladder and decreased body weight gain between days 0-56. LOAEL: Not established (♀).	1410046
78-week dietary	Mouse	NOAEL: 147/185mg/kg bw/day(♂/♀) LOAEL: 599/758 mg/kg bw/day (♂/♀), based on increased incidence of mortality, generalized soiled fur, skin lesions (principally in the anogenital region (♂), abnormal penis, chronic ulcerative dermitis and/or an abscess in the preputial gland (♂), increased incidence of stones in the urinary bladder, increased incidence and severity of several urinary bladder histopathologies including urothelial hyperplasia, interstitial edema, suburothelial mixed cell infiltrate, intramuscular inflammatory cell infiltrate, serosal mixed cell infiltrate, induced arteritis, and adenomyosis, wasted appearance (♂) and decreased body weight gain (♂).	1410056

Study Type	Species	Results[a] (mg/kg/day in M/F)	Reference
		Bladder oncogenicity: Incidence of M-Transitional cell carcinoma, B-Transitional cell papilloma and M-Urethral transitional cell carcinoma (♂) **Interim sacrifice** - no adverse effects **Oncogenic in mice, secondary to hyperplastic urolithiasis.**	
2-year dietary FOB and motor activity were assessed in the satellite group week 50	Rat	NOAEL:234/313.4 mg/kg bw/day (♂/♀) LOAEL: Not established.	1410055
Multi-generation	Rat	**Parental:** NOAEL: 245/56 mg/kg bw/day (♂/♀) LOAEL: 945/264 mg/kg bw/day (♂/♀), based on clinical observations such as tilted head and emaciation, increased urination, kidney stones with pelvic dilation, one mortality (F_1 ♂), decreased liver weight (F1 ♂) and body weight (F_1 ♀) and increased kidney weight (F_0/F_1 ♀). **Offspring Toxicity**: NOAEL: 261/353 mg/kg bw/day (♂/♀) LOAEL: 946/968 mg/kg bw/day (♂/♀), based on kidney/urinary stones and pelvic dilation (F_1/F_2). **Reproductive:** NOAEL: 992/1284 mg/kg bw/day (♂/♀) LOAEL: Not established.	1410057
Developmental toxicity in rodents	Rat	**Maternal** NOAEL: 200 mg/kg bw/day LOAEL: 1000 mg/kg bw/day, based on decreased food consumption (gestation day 6-20 , ♂) and body weight gain and increased sediment in urinary bladder, urethra & kidney with dilation. **Developmental:** NOAEL: 200 mg/kg bw/day LOAEL: 1000 mg/kg bw/day, based on decreased fetal weights, retarded ossification of several bones including metacarpals, sternebrae, sacral and caudal vertebrae and phalanges and increased incidence of wavy ribs.	1410058

Study Type	Species	Results[a] (mg/kg/day in M/F)	Reference
Developmental toxicity in non-rodents	Rabbit	**Maternal** NOAEL: 125 mg/kg bw/day LOAEL: 500 mg/kg bw/day, based on 1 ♀ sacrificed in extremis (gestation day 15), decreased food consumption and body weight gain, increased sediment in the urinary bladder and kidney and decreased faeces **Developmental :** NOAEL: 125 mg/kg bw/day LOAEL: 500 mg/kg bw/day, based on decreased fetal weight and increased incidence of runts.	1410059
GENOTOXICITY			
Gene mutations in bacteria (reverse)	Salmonella typhimurium strains TA 98, TA 100, TA 102, TA 1535 and TA 1537	Negative	1410049
Gene mutations in bacteria (reverse)	Salmonella typhimurium strains TA 98, TA 100, TA 102, TA 1535 and TA 1537	Negative	1410048
Gene mutations in mammalian cells in vitro (forward mutation)	Chinese hamster V79 lung cells (HGPRT locus)	Negative	1410053
Gene mutations in mammalian cells in vitro (forward mutation)	Chinese hamster V79 lung cells (HGPRT locus)	Negative	1410052
Chromosome aberrations in vitro	Chinese hamster V79 lung cells	Negative	1410051
Chromosome aberrations in vitro	Chinese hamster V79 lung cells	Negative	1410052
Micronucleus assay (in vivo)	Mouse	Negative	1410054
NEUROTOXICITY			
Acute (gavage)	Rat	NOAEL: 2000 mg/kg bw/day LOAEL: Not established.	1410060
90-day dietary	Rat	NOAEL: 411/527 mg/kg bw/day (♂/♀) LOAEL: Not established.	1410061
BYH 18636 CARBOXYLIC ACID METABOLITE STUDIES			
GENOTOXICITY			
Gene mutations in bacteria (reverse)	Salmonella typhimurium strains TA 98, TA 100, TA 102, TA 1535 and TA 1537	Negative	1410074

Study Type	Species	Results[a] (mg/kg/day in M/F)		Reference
Chromosome aberrations in vitro	Chinese hamster V79 lung cells	Negative		1410073
Gene mutations in mammalian cells in vitro (forward mutation)	Chinese hamster V79 lung cells (HGPRT locus)	Negative		1410072
ACUTE STUDIES				
Oral (Acute Toxic Class Method)	Rat	LD_{50} > 2000 mg/kg bw	Low Toxicity	1410071
SHORT TERM TOXICITY				
90-day dietary with minimal neurotoxicity tested (limited FOB and motor activity)	Rat	NOAEL: 972/1170 mg/kg bw/day (♂/♀) LOAEL: Not established (♂/♀)		1410070
BYH 18636 SULFONAMIDE METABOLITE STUDIES				
GENOTOXICITY				
Gene mutations in bacteria	Salmonella typhimurium strains TA 98, TA 100, TA 102, TA 1535 and TA 1537	Negative		1410069
ACUTE STUDIES				
Oral (Acute Toxic Class Method)	Rat	LD_{50} > 2000 mg/kg bw	Low Toxicity	1410031
SHORT TERM TOXICITY				
28-day dietary with minimal neurotoxicity tested (limited FOB and motor activity)	Rat	NOAEL: 800/917 mg/kg bw/day (♂/♀) LOAEL: Not established. (♂/♀)		1410067
BYH 18636 N-DESMETHYL METABOLITE STUDIES				
GENOTOXICITY				
Gene mutations in bacteria (reverse)	Salmonella typhimurium strains TA 98, TA 100, TA 102, TA 1535 and TA 1537		Negative	1410066
Chromosome aberrations in vitro	Chinese hamster V79 lung cells		Negative	1410065
Gene mutations in mammalian cells in vitro (forward mutation)	Chinese hamster V79 lung cells (HGPRT locus)		Negative	1410064
ACUTE STUDIES				
Oral (Acute Toxic Class Method)	Rats	LD_{50} > 2000 mg/kg bw	Low Toxicity	1410063

Study Type	Species	Results[a] (mg/kg/day in M/F)	Reference
SHORT TERM TOXICITY			
28-day dietary with minimal neurotoxicity tested (limited FOB and motor activity)	Rat	NOAEL: 1045/1133 mg/kg bw/day (♂/♀) LOAEL: Not established (♂/♀)	1410062
METABOLISM			
Metabolism	Rat	[Thiophene-4-^{14}C] BYH 18636 was administered in 0.5% aqueous tragacanth as a single oral low dose (2 mg/kg bw - both sexes; bile-duct cannulation in ♂ only), a single oral high dose (100 mg/kg bw; 1:50 mixture of radiolabeled:non-radiolabeled test compound; males only), or a repeat oral low dose (2 mg/kg bw; ♂ only) of non-radiolabeled test material (14 days) followed by a single dose (2 mg/kg bw) of radiolabeled test material. [Dihydrotriazole-3-^{14}C] BYH 18636 was administered in 0.5% aqueous tragacanth as a single oral low dose (2 mg/kg bw; ♂ only). Animals were sacrificed 48 hours after dose administration. Quantitative whole body autoradiography (QWBA) was assessed in ♂ at various time points after administration of a single oral low dose (3 mg/kg bw) of [Thiophene-4-^{14}C] or [Dihydrotriazole-3-^{14}C] BYH 18636 in 0.5% aqueous tragacanth. Results are presented for both labels combined unless otherwise noted. **Absorption:** Approximately 92-100% of the administered dose (AD) was recovered. Absorption was rapid (Tmax = 0.6-1 hours). Approximately 42-55% of the AD was absorbed. AUC values were proportional to dose. **Excretion:** Elimination included a fast initial phase ($t_{1/2}$ 0.12-0.55 hours) and a slower terminal phase ($t_{1/2}$ 8-36 hours). Approximately 87-97% (low dose) and 73% (high dose) of the AD was excreted within 24 hours post-dosing, with excretion nearly complete (99%) within 48 hours. Urinary and fecal excretion accounted for 42-54% and 44-58% of the AD, respectively. Excretion via the bile (1.4%) and expired air (0.01%) was negligible. **Distribution:** Residue levels remaining in tissues 48 hours post-dosing were low (0.5-0.7% of the AD). Slightly different distribution patterns were noted for the different labels. For the thiophene label, the highest levels of radioactivity were detected in the liver (0.2-0.3% low dose; 0.06% high dose), skin (0.04-0.08%), GIT (0.02% ♂ single low dose; 0.12% repeat low dose; 0.17% ♀ single low dose; 0.4% high dose), carcass (0.07-0.14%), lung (0.004-0.01%) and testis (0.007-0.01%). The highest levels of radioactivity when corrected for tissue mass were detected in the liver, lung, testis, kidney, skin, GIT, perirenal fat, and thyroid gland. For the dihydrotriazole label, the highest levels of radioactivity were detected in the carcass (0.32%), GIT (0.07%), skin (0.04%), liver (0.04%), and plasma (0.01%). When concentrations were corrected for tissue mass, the highest levels of radioactivity were detected in the thyroid gland, plasma, liver, adrenal gland, carcass, and GIT.	1518918 1410026 1410027 1410029 1410030

Study Type	Species	Results[a] (mg/kg/day in M/F)	Reference
		For both labels, quantitative whole body autoradiography revealed highest levels of radioactivity (µg/g) in the liver, blood, kidney, lung, adrenal gland, myocardium, brown fat, skin, salivary gland, pineal body, thyroid gland, and pituitary gland at 1 hr post-dosing. After 7 days, all values were below the limit of detection, except for the nasal mucosa (both labels) and the liver and testes (thiophene-label only), which had very low concentrations. **Metabolism:** The parent compound underwent limited metabolism and was the major component in excreta (81-92% of the AD). For the thiophene label, one minor metabolite (BYH 18636-sulfonamide-carboxylic acid; 1-2%) and one trace metabolite (BYH 18636-thienesaccharine; 0.1-0.2%) were detected in urine. Only the parent was detected in feces and bile. BYH-18636-sulfonamide was identified as a tentative metabolite in urine and feces (0.7-1.5%), but was also present at trace amounts in the dosing suspensions. For the dihydrotriazole label, 5 trace metabolites (<1%) were identified: methyl carbamate, BYH 18636-OMT, BYH 18636-MMT and 2 unknowns. [Thiophene-4-^{14}C] BYH 18636 was metabolized through hydrolysis resulting in cleavage of the urea group and release of the thiophene-sulfonamide moiety. A second hydrolysis of the methyl ester occurred, yielding BYH 18636-sulfonamide-carboxylic acid, which in turn was cyclized to BYH 18636-thieno-saccharine, forming a new sulfonamide bond. [Dihydrotriazole-3-^{14}C] BYH 18636 was metabolized by hydrolysis resulting in cleavage of the urea group and the formation of BYH-18636-MMT. Desmethylation of BYH 18636-MMT led to BYH 18636-OMT and subsequent cleavage of the triazolinone moiety to methyl-carbamate.	

a Effects observed in males as well as females unless otherwise reported

Table 4 Toxicology Endpoints for Use in Health Risk Assessment for Thiencarbazone Methyl

Exposure Scenario	Dose (mg/kg bw/day)	Study	Endpoint	UF/SF[1] or Target MOE[2]
Acute dietary				
	ARfD = not required			
Chronic Dietary	NOAEL = 117	12-month capsule dog	- based on increased mean urinary protein, calculi and abnormal consistency, transitional cell hyperplasia, slight congestion, slight haemorrhage, slight inflammation, minimal calculi and moderate ulceration in the bladder and decreased body weight gain between days 0-56. (♂)	100
	ADI = 1.17 mg/kg bw/day			
Short-term Dermal and Inhalation	NOAEL = 149	90-day dietary dog	- based on calculi, haemorrhage, inflammatory changes and epithelial hyperplasia in the bladder.	100

1 Dietary scenarios

2 Exposure scenarios

Table 5 Integrated Food Residue Chemistry Summary

NATURE OF THE RESIDUE IN CORN (Romario variety)			PMRA # 1410084, 1410083, 1410082, 1410081, 1410080, 1410079
Test Site	Greenhouse		
Treatment	Pre-emergence application to soil		
Rate	45 g a.i./ha (nominal)		
End-use product	WG75 (thiencarbazone-methyl + safener (cyprosulfamide) 1:1 ratio)		
Application Timing	Pre-emergence application		
Matrix	PHI (days)	[dihydrotriazole-3-14C] BYH18636 TRR (ppm)	[thiophene-4-14C] BYH18636 TRR (ppm)
Forage	BBCH 83	0.005	0.005
Stover	BBCH 99	0.016	0.013
Kernels	BBCH 99	0.001	0.001
Radiolabel Position	[dihydrotriazole-3-14C] BYH18636		
Metabolites Identified	Major Metabolites (> 10% TRR)		Minor Metabolites (< 10% TRR)
Forage	MMT-glucoside, Triazolinone-carboxamide		BYH 18636, MMT
Stover	MMT-glucoside, Triazolinone-carboxamide		BYH 18636, N-desmethyl, carboxylic acid, MMT
Kernels	Not analysed due to low absolute values of TRRs		
Radiolabel Position	[thiophene-4-14C] BYH18636		
Metabolites Identified	Major Metabolites (> 10% TRR)		Minor Metabolites (< 10% TRR)
Forage	hydroxy-sulfonamide-carboxylic acid and conjugate + hydroxy-thienosaccharine and conjugate		BYH 18636, sulfonamide, hydroxy-sulfonamide-glycoside, hydroxy-sulfonamide-glyceric acid ester, sulfonamide-carboxylic acid
Stover	hydroxy-sulfonamide-carboxylic acid and conjugate, hydroxy-thienosaccharine and conjugate		BYH 18636, N-desmethyl, sulfonamide, hydroxy-sulfonamide, hydroxy-sulfonamide-glycoside, hydroxy-sulfonamide-glyceric acid ester, sulfonamide-carboxylic acid
Kernels	Not analysed due to low absolute values of TRRs		
NATURE OF THE RESIDUE IN CORN (Romario variety)			
Test Site	Greenhouse		
Treatment	Early post-emergent; foliar		
Rate	15 g a.i./ha As well, experiments were conducted at 30 g a.i./ha (2 plants) and 75 g a.i./ha (1 plant) in an attempt to further identify metabolites in kernels. Results from the extra samples were inconclusive as TRRs were low in the plants treated at 30 g a.i./ha and phytotoxic effects were observed in the plants treated at 75 g a.i./ha.		

NATURE OF THE RESIDUE IN CORN (Romario variety)			PMRA # 1410084, 1410083, 1410082, 1410081, 1410080, 1410079
End-use product	OD 04 (thiencarbazone-methyl + safener isoxadifen-ethyl 1:3 ratio)		
Application Timing	Application at BBCH 13 – 16		
Matrix	PHI (days)	[dihydrotriazole-3-14C] BYH18636 TRR (ppm)	[thiophene-4-14C] BYH18636 TRR (ppm)
Forage	BBCH 83	0.031	0.051
Stover	BBCH 99	0.054	0.083
Kernels	BBCH 99	0.002	0.001
Radiolabel Position	[dihydrotriazole-3-14C] BYH18636		
Metabolites Identified	Major Metabolites (> 10% TRR)	Minor Metabolites (< 10% TRR)	
Forage	BYH 18636, N-desmethyl-hydroxy MMT-glucoside	N-desmethyl, MMT, N-desmethyl-hydroxy-glycoside, N-desmethyl-carboxylic acid, hydroxy-glycoside, carboxylic acid, triazolinone-carboxamide, OMT and OMT-glycoside	
Stover	BYH 18636, MMT-glucoside	N-desmethyl, MMT, N-desmethyl-hydroxy , N-desmethyl-hydroxy-glycoside, N-desmethyl-carboxylic acid, carboxylic acid, triazolinone-carboxamide, OMT and OMT-glycoside	
Kernels	Not analysed due to low absolute values of TRRs		
Radiolabel Position	[thiophene-4-14C] BYH18636		
Metabolites Identified	Major Metabolites (> 10% TRR)	Minor Metabolites (< 10% TRR)	
Forage	N-desmethyl-hydroxy	BYH 18636, N-desmethyl, N-desmethyl-hydroxy-glycoside, N-desmethyl-carboxylic acid, hydroxy-glycoside, carboxylic acid, sulfonamide, hydroxy-sulfonamide, hydroxy-sulfonamide-glycoside and minor unidentified compound, hydroxy-sulfonamide-glyceric acid ester, hydroxy-sulfonamide-carboxylic-acid, hydroxy-thienosaccharine and conjugates of both, sulfonamide-carboxylic acid	
Stover	N-desmethyl-hydroxy, hydroxy-sulfonamide-glycoside and minor unidentified compound	BYH 18636, N-desmethyl, N-desmethyl-hydroxy-glycoside, N-desmethyl-carboxylic acid, hydroxy-glycoside, carboxylic acid, sulfonamide, hydroxy-sulfonamide-glyceric acid ester, hydroxy-sulfonamide-carboxylic-acid, hydroxy-thienosaccharine and conjugates of both, sulfonamide-carboxylic acid	
Kernels	Not analysed due to low absolute values of TRRs		
NATURE OF THE RESIDUE IN CORN (Romario variety)			
Test Site	Greenhouse		
Treatment	Post-emergent; foliar		

NATURE OF THE RESIDUE IN CORN (Romario variety)			PMRA # 1410084, 1410083, 1410082, 1410081, 1410080, 1410079
Rate	30 g a.i./ha + 15 g a.i./ha (Total rate of 45 g a.i./ha/season)		
End-use product	OD 04 (thiencarbazone-methyl + safener isoxadifen-ethyl 1:3 ratio)		
Application Timing	Application at V6 & V12		
Matrix	PHI (days)	[dihydrotriazole-3-14C] BYH18636 TRR (ppm)	[thiophene-4-14C] BYH18636 TRR (ppm)
Forage	BBCH 83	0.022	0.014
Stover	BBCH 99	0.047	0.063
Kernels	BBCH 99	0.004	0.005
Radiolabel Position	[dihydrotriazole-3-14C] BYH18636		
Metabolites Identified	Major Metabolites (> 10% TRR)	Minor Metabolites (< 10% TRR)	
Forage	MMT-glucoside	BYH 18636, N-desmethyl, N-desmethyl-hydroxy, N-desmethyl-hydroxy-glycoside, N-desmethyl-carboxylic acid, hydroxy-glycoside, MMT, OMT and OMT-glycoside, triazolinone-carboxamide	
Stover	MMT-glucoside	BYH 18636, N-desmethyl, N-desmethyl-hydroxy-glycoside, N-desmethyl-carboxylic acid, carboxylic acid, triazolinone-carboxamide, MMT, OMT and OMT-glycoside	
Kernels	Not detected	MMT-glucoside	
Radiolabel Position	[thiophene-4-14C] BYH18636		
Metabolites Identified	Major Metabolites (> 10% TRR)	Minor Metabolites (< 10% TRR)	
Forage	hydroxy-sulfonamide-carboxylic acid and conjugate + hydroxy-thienosaccharine and conjugate	BYH 18636, N-desmethyl-hydroxy, N-desmethyl-hydroxy-glycoside, N-desmethyl-carboxylic acid, sulfonamide, hydroxy-sulfonamide , hydroxy-sulfonamide-glycoside, sulfonamide-carboxylic acid, carboxylic acid , thienosaccharine	
Stover	hydroxy-sulfonamide-carboxylic acid and conjugate	BYH 18636, N-desmethyl, N-desmethyl-hydroxy, N-desmethyl-hydroxy-glycoside, N-desmethyl-carboxylic acid, sulfonamide, hydroxy-sulfonamide , hydroxy-sulfonamide-glycoside, hydroxy-sulfonamide-glyceric acid ester, sulfonamide-carboxylic acid, carboxylic acid , thienosaccharine, hydroxy-thienosaccharine and conjugate	

NATURE OF THE RESIDUE IN CORN (Romario variety)		PMRA # 1410084, 1410083, 1410082, 1410081, 1410080, 1410079
Kernels	Not detected	hydroxy-sulfonamide-glyceric acid ester, sulfonamide-carboxylic acid, hydroxy-sulfonamide-carboxylic acid and conjugate + hydroxy-thienosaccharine and conjugate, thienosaccharine

NATURE OF THE RESIDUE IN WHEAT		PMRA # 1410078, 1410077
Test Site	Greenhouse	
Treatment	Sprayer 5 weeks after planting (BBCH 14 – 15)	
Rate	15 g a.i./ha	
End-use product	OD 70 (thiencarbazone-methyl + safener (mefenpyr-diethyl 1: 6 ratio)	
Application Timing	Early post-emergence application	
Matrix	[dihydrotriazole-3-14C] BYH18636 TRR (ppm)	[thiophene-4-14C] BYH18636 TRR (ppm)
Forage	0.37	0.27
Hay	0.29	0.31
Straw	0.28	0.39
Grain	0.014	0.011
Radiolabel Position	[dihydrotriazole-3-14C] BYH18636	
Metabolites Identified	Major Metabolites (> 10% TRR)	Minor Metabolites (< 10% TRR)
Forage	BYH 18636, N-desmethyl, hydroxy	N-desmethyl-glycoside, Triazolinone-carboxamide, N-desmethyl-hydroxy, N-desmethyl-hydroxy-glycoside, hydroxy-glycoside, MMT-glucoside, OMT and OMT-glycoside
Hay	MMT-glucoside, N-desmethyl,	BYH 18636, N-desmethyl-glycoside, Triazolinone-carboxamide, N-desmethyl-hydroxy, N-desmethyl-hydroxy-glycoside, hydroxy, hydroxy-glycoside, MMT-glucoside, OMT and OMT-glycoside
Straw	MMT-glucoside, N-desmethyl	BYH 18636, N-desmethyl-glycoside, N-desmethyl-hydroxy, N-desmethyl-hydroxy-glycoside, hydroxy, hydroxy-glycoside, OMT and OMT-glycoside, Triazolinone-carboxamide, MMT
Grain	N-desmethyl	BYH 18636, N-desmethyl-glycoside, N-desmethyl-hydroxy, N-desmethyl-hydroxy-glycoside, hydroxy, hydroxy-glycoside, carboxylic acid, MMT-glucoside, OMT and OMT-glycoside, Triazolinone-carboxamide, MMT

NATURE OF THE RESIDUE IN CORN (Romario variety)		PMRA # 1410084, 1410083, 1410082, 1410081, 1410080, 1410079
Radiolabel Position	[thiophene-4-14C] BYH18636	
Metabolites Identified	Major Metabolites (> 10% TRR)	Minor Metabolites (< 10% TRR)
Forage	BYH 18636, N-desmethyl, hydroxy	N-desmethyl-glycoside, N-desmethyl-hydroxy, N-desmethyl-hydroxy-glycoside, hydroxy-glycoside, sulfonamide, hydroxy-sulfonamide, hydroxy-sulfonamide-glycoside, hydroxy-sulfonamide-acetyl-glycoside
Hay	N-desmethyl, N-desmethyl-hydroxy	BYH 18636, N-desmethyl-glycoside, N-desmethyl-hydroxy-glycoside, hydroxy, hydroxy-glycoside, sulfonamide, hydroxy-sulfonamide, hydroxy-sulfonamide-glycoside, hydroxy-sulfonamide-acetyl-glycoside, hydroxy-sulfonamide-glyceric acid ester, hydroxy-sulfonamide-carboxylic acid, hydroxy-thienosaccharine, sulfonamide-carboxylic acid
Straw	N-desmethyl, sulfonamide	BYH 18636, N-desmethyl-glycoside, N-desmethyl-hydroxy, N-desmethyl-hydroxy-glycoside, hydroxy, hydroxy-glycoside, carboxylic acid, sulfonamide, hydroxy-sulfonamide, hydroxy-sulfonamide-glycoside, hydroxy-sulfonamide-acetyl-glycoside, hydroxy-sulfonamide-glyceric acid ester, hydroxy-sulfonamide-carboxylic acid, , hydroxy-thienosaccharine, sulfonamide-carboxylic acid
Grain	N-desmethyl, N-desmethyl-hydroxy, hydroxy-glycoside	BYH 18636, N-desmethyl-glycoside, N-desmethyl-hydroxy-glycoside, hydroxy, hydroxy-sulfonamide, sulfonamide

CONFINED ACCUMULATION IN ROTATIONAL CROPS		PMRA # 1410107, 1410107, 1410109, 1410110, 1410111, 1410112
Radiolabel Position	[thiophene-4-14C] BYH18636	[dihydrotriazole-3-14C] BYH18636
Test site	Bare sandy loam soil. Outdoor first rotation. Greenhouse second and third rotation.	
Formulation used for trial	WDG formulation	
Application rate and timing	Separate studies were conducted at application rates of 15, 30, and 45 g a.i./ha	

NATURE OF THE RESIDUE IN CORN (Romario variety)	PMRA # 1410084, 1410083, 1410082, 1410081, 1410080, 1410079

Two studies ([thiophene-4-14C] BYH18636 label and the [dihydrotriazole-3-14C] BYH18636 label) were conducted for each of the treatment rates of 15, 30, and 45 g a.i./ha. The major and minor metabolites identified in the table below reflect the results from the trials conducted at 15 g a.i./ha (twofold the Canadian approved rate) and 45 g a.i./ha. The results from the 30 g a.i./ha study were not reported due to the similarity to the reported results.

The metabolic profile as observed in confined rotational crops was consistent with the corresponding metabolism studies performed in primary crops (corn and wheat). The results underline the cleavage at the sulfonylurea chain to result in the formation of BYH 18636-MMT as the predominant residue in soil taken up by plants. The uptake is followed by conjugation to BYH 18636-MMT-glucoside in plants.

Although, a field accumulation study would not have been necessary for Canadian purposes (as per DIR 98-02) since the 15 g a.i./ha rate did not result in residues >0.01 ppm for any of the analytes, field accumulation studies were triggered as a result of the confined crop rotational studies conducted at the 45 g a.i./ha rate due to measurable residues of parent and the metabolites in soybeans and wheat.

Metabolites Identified		Major Metabolites (> 10% TRR)		Minor Metabolites (< 10% TRR)	
Matrix	PBI (days)	[thiophene-4-14C] BYH18636	[dihydrotriazole-3-14C] BYH18636	[thiophene-4-14C] BYH18636	[dihydrotriazole-3-14C] BYH18636
Soybean forage 45 g a.i./ha	90	TRRs < 0.01 ppm			
	270	-	MMT, MMT-glucoside	-	BYH 18636, Hydroxy, carboxylic acid, triazolinone-carboxamide
Soybean hay 45 g a.i./ha	90	BYH 18636, carboxylic acid	BYH 18636, carboxylic acid, MMT-glucoside	Hydroxy, N-desmethyl-hydroxy, sulfonamide-carboxylic acid, hydroxy-thienosaccharine-glycoside	Hydroxy, MMT, triazolinone-carboxamide
	270	Carboxylic acid, hydroxy-thienosaccharine -glycoside	MMT-glucoside	BYH 18636	BYH 18636, Hydroxy, carboxylic acid, MMT, triazolinone-carboxamide, hydroxy-glycoside
Soybean straw 45 g a.i./ha	90	TRRs < 0.01 ppm			
	270				

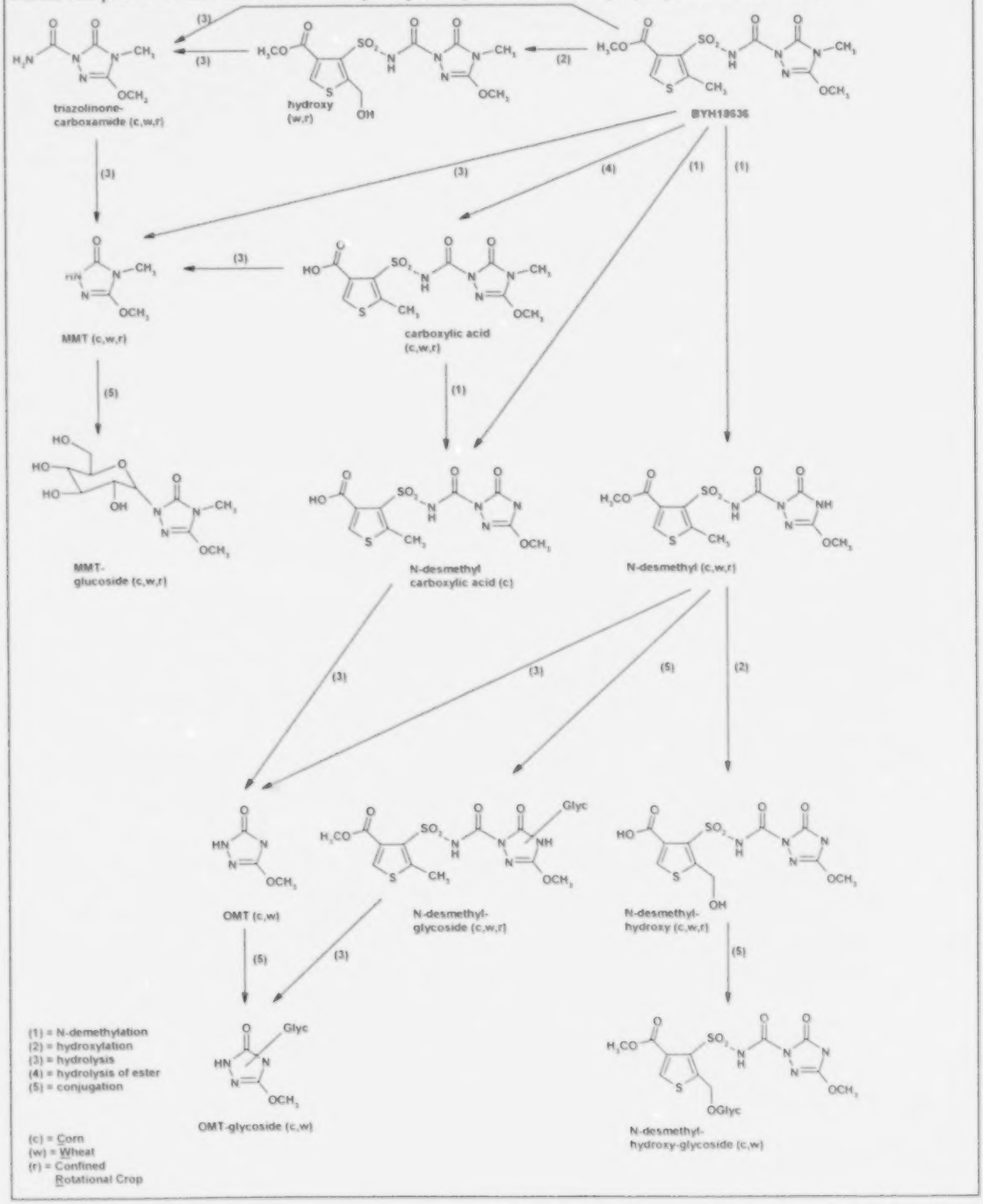
NATURE OF THE RESIDUE IN CORN (Romario variety)				PMRA # 1410084, 1410083, 1410082, 1410081, 1410080, 1410079	
Soybean seeds 45 g a.i./ha	90	BYH 18636	BYH 18636, MMT-glucoside	Hydroxy, N-desmethyl-hydroxy, carboxylic acid, sulfonamide-carboxylic acid, hydroxy-thienosaccharine-glycoside	Hydroxy, MMT, triazolinone-carboxamide
	270	BYH 18636	BYH 18636, MMT-glucoside	hydroxy, N-desmethyl-hydroxy, carboxylic acid, hydroxy-thienosaccharine-glycoside	Hydroxy, MMT, triazolinone-carboxamide, hydroxy-glycoside
Wheat grain 45 g a.i./ha	90	TRRs < 0.01 ppm			
	270				
Wheat forage 45 g a.i./ha	90	N-desmethyl-hydroxy	MMT-glucoside	BYH 18636, N-desmethyl, hydroxy, carboxylic acid, sulfonamide, hydroxy-sulfonamide-glycoside, sulfonamide-carboxylic acid, hydroxy-thienosaccharine-glycoside	BYH 18636, N-desmethyl, hydroxy, MMT, triazolinone-carboxamide
	270	TRRs < 0.01 ppm			
Wheat hay 45 g a.i./ha	90	N-desmethyl-hydroxy	triazolinone-carboxamide, MMT-glucoside	BYH 18636, N-desmethyl, hydroxy, carboxylic acid, sulfonamide, hydroxy-sulfonamide-glycoside, sulfonamide-carboxylic acid, hydroxy-thienosaccharine-glycoside	BYH 18636, N-desmethyl, hydroxy, carboxylic acid, MMT, hydroxy-glycoside
	270	-	MMT-glucoside	-	hydroxy, MMT, triazolinone-carboxamide

NATURE OF THE RESIDUE IN CORN (Romario variety)					PMRA # 1410084, 1410083, 1410082, 1410081, 1410080, 1410079
Wheat straw 45 g a.i./ha	90	N-desmethyl-hydroxy	triazolinone-carboxamide, MMT-glucoside	BYH 18636, N-desmethyl, hydroxy, carboxylic acid, sulfonamide, hydroxy-sulfonamide-glycoside, sulfonamide-carboxylic acid, hydroxy-thienosaccharine-glycoside	BYH 18636, N-desmethyl, hydroxy, carboxylic acid, MMT
	270	N-desmethyl-hydroxy	MMT-glucoside	BYH 18636, hydroxyl, carboxylic acid, hydroxy-sulfonamide, hydroxy-thienosaccharine-glycoside	BYH 18636, N-desmethyl, hydroxy, carboxylic acid, MMT, triazolinone-carboxamide
Turnip tops 45 g a.i./ha	90	Plant injury from herbicidal effects, therefore, no samples from this rotation.			
	180	TRRs < 0.01 ppm			
	270				
Turnip root 45 g a.i./ha	90	Plant injury from herbicidal effects, therefore, no samples from this rotation.			
	180	TRRs < 0.01 ppm			
	270				
Swiss chard 15 g a.i./ha	29	BYH 18636	BYH 18636, MMT	sulfonamide	< 0.01 ppm
	118	TRRs < 0.01 ppm			
	247				
Turnip roots 15 g a.i./ha	29	TRRs < 0.01 ppm			
	118				
	247				

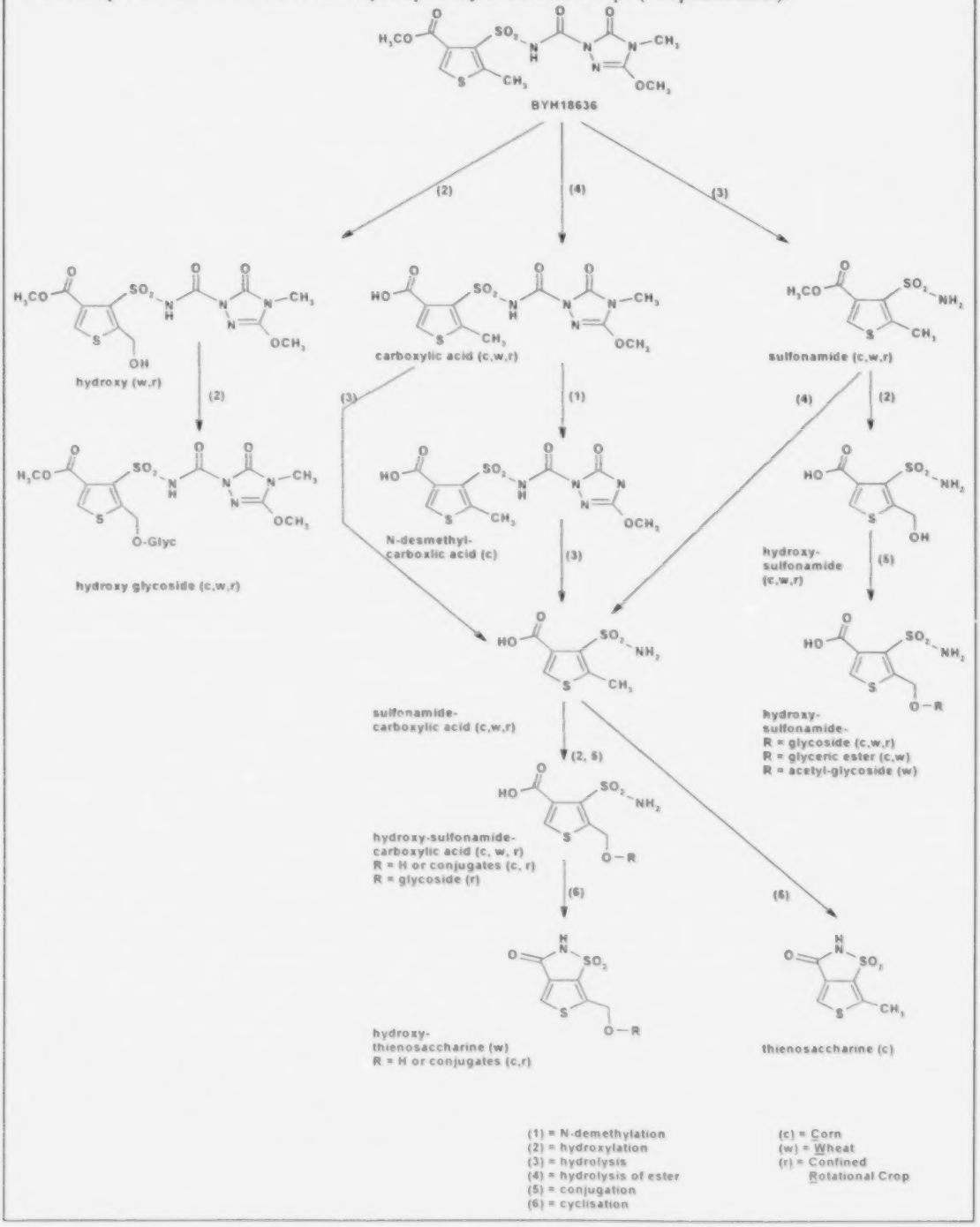
NATURE OF THE RESIDUE IN CORN (Romario variety)					PMRA # 1410084, 1410083, 1410082, 1410081, 1410080, 1410079
Turnip tops 15 g a.i./ha	29	N-desmethyl-hydroxy, hydroxy-sulfonamide-carboxylic acid	MMT-glucoside, MMT	hydroxy-thienosaccharine-glycoside	BYH 18636, triazolinone-carboxamide
	118	TRRs < 0.01 ppm			
	247				
Wheat hay 15 g a.i./ha	29	N-desmethyl-hydroxy, hydroxy-thienosaccharine-glycoside	triazolinone-carboxamide, MMT-glucoside	N-desmethyl, hydroxy, sulfonamide, hydroxy-sulfonamide-glycoside, hydroxy-sulfonamide-carboxylic acid	BYH 18636, N-desmethyl, hydroxy, MMT
	118	TRRs < 0.01 ppm			
	247				
Wheat straw 15 g a.i./ha	29	N-desmethyl-hydroxy, hydroxy-thienosaccharine-glycoside	triazolinone-carboxamide, MMT-glucoside	BYH 18636, N-desmethyl, hydroxy, carboxylic acid, sulfonamide, hydroxy-sulfonamide, hydroxy-sulfonamide-glycoside, hydroxy-sulfonamide-carboxylic acid	BYH 18636, N-desmethyl, hydroxy, MMT, carboxylic acid
	118	N-desmethyl, hydroxy	MMT-glucoside	N-desmethyl, hydroxy, carboxylic acid, sulfonamide, hydroxy-sulfonamide, hydroxy-thienosaccharine-glycoside	BYH 18636, N-desmethyl, hydroxy, carboxylic acid, MMT, triazolinone-carboxamide
	247	TRRs < 0.01 ppm			

NATURE OF THE RESIDUE IN CORN (Romario variety)					PMRA # 1410084, 1410083, 1410082, 1410081, 1410080, 1410079
Wheat forage 15 g a.i./ha	29	-	triazolinone-carboxamide, MMT-glucoside	BYH 18636, N-desmethyl, hydroxy, N-desmethyl-hydroxy, sulfonamide, hydroxy-sulfonamide, hydroxy-sulfonamide-glycoside, hydroxy-sulfonamide-carboxylic acid, hydroxy-thienosaccharine-glycoside	BYH 18636, N-desmethyl, hydroxy, MMT
	118	TRRs < 0.01 ppm			
	247	TRRs < 0.01 ppm			
Wheat grain 15 g a.i./ha	29	-	-	BYH 18636, N-desmethyl, hydroxy, N-desmethyl-hydroxy, hydroxy-sulfonamide-glycoside, hydroxy-sulfonamide-carboxylic acid, hydroxy-thienosaccharine-glycoside	BYH 18636, N-desmethyl, hydroxy, MMT, triazolinone-carboxamide, MMT-glucoside
	118	TRRs < 0.01 ppm			
	247	TRRs < 0.01 ppm			

Metabolic profile of thiencarbazone-methyl in primary and rotated crops (dihydrotriazole label).

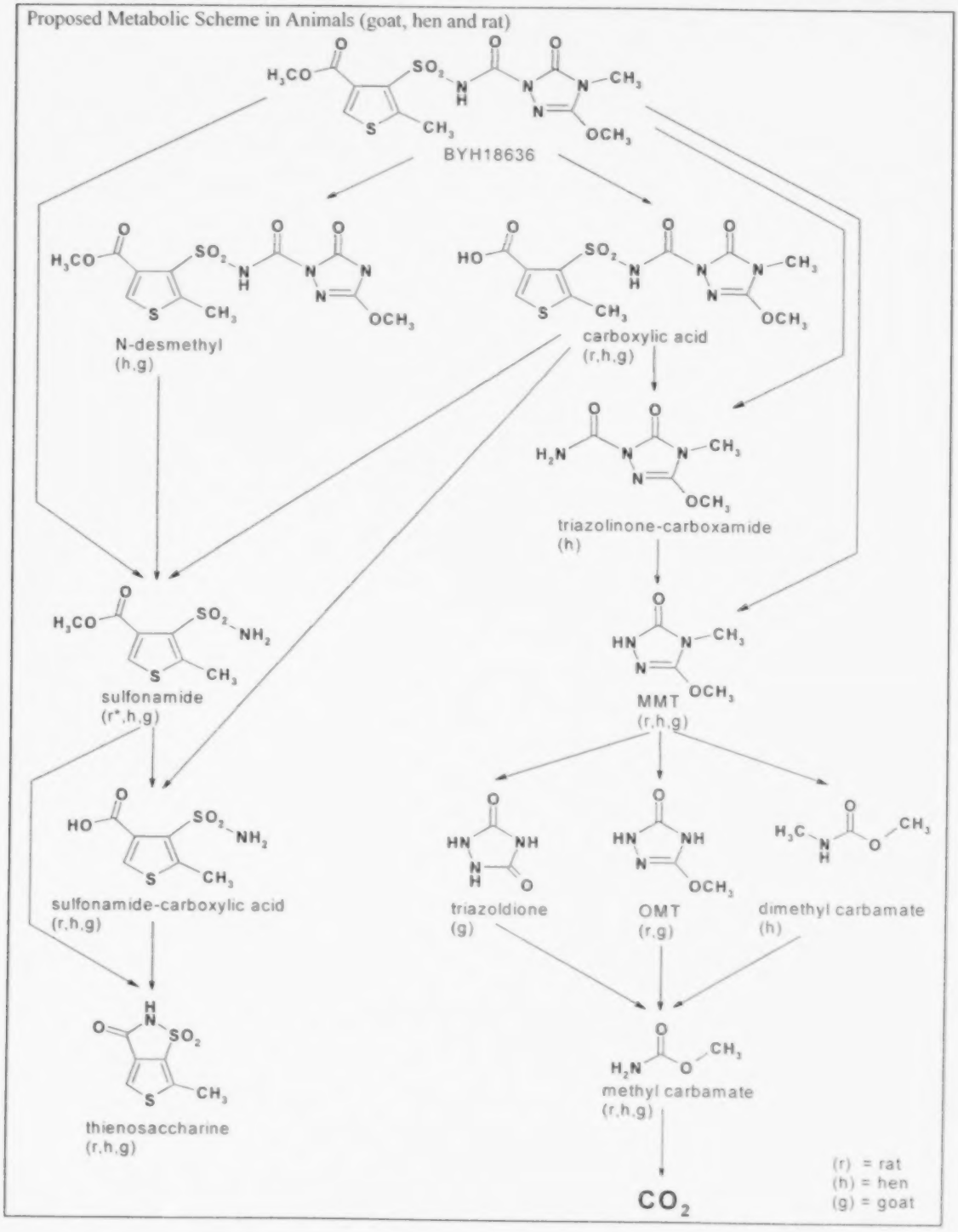


Metabolite profile of thiencarbazone-methyl in primary and rotated crops (thiophene label).



NATURE OF THE RESIDUE IN LAYING HEN			PMRA # 1410085, 1410086	
Six laying hens were orally dosed on 14 consecutive days in time intervals of 24 hours with [Thiophene-4-14C]-BYH18636] at an actual daily dose level of 1.98 mg/kg bw/day corresponding to an exaggerated dose of 25.22 mg/kg in the daily diet. Six laying hens were also orally dosed on 14 consecutive days in time intervals of 24 hours with [Dihydrotriazole-14C]-BYH18636 at an actual daily dose level of 2.06 mg/kg bw/day corresponding to an exaggerated dose of 27.16 mg/kg in the daily diet. The edible organs and tissues, eggs and excreta were analysed for the active ingredient (a.i.) and metabolites. Samples were extracted using acetonitrile/water and acetonitrile/water/acetic acid, purified by solid phase extraction and analysed by HPLC-MS/MS.				
Matrices			% of Administered Dose	
			[Thiophene-4-14C]	[Dihydrotriazole-3-14C]
Excreta			91.03	92.58
Liver			0.016	0.012
Kidney			0.006	0.003
Eggs			0.001	0.009
Muscle			0.003	0.133
Fat			0.002	0.04
Skin (without fat)			<0.001	0.002
Metabolites identified	Major Metabolites (> 10% TRR)		Minor Metabolites (< 10% TRR)	
Radiolabel Position	[Thiophene-4-14C]	[Dihydrotriazole-3-14C]	[Thiophene-4-14C]	[Dihydrotriazole-3-14C]
Eggs	BYH 18636	Methyl carbamate, dimethyl carbamate, MMT	Thienosaccharine + sulfonamide-carboxylic acid	BYH 18636, triazolinone-carboxamide
Fat	Not analyzed	Methyl carbamate, dimethyl carbamate, MMT	Not analyzed	BYH 18636, triazolinone-carboxamide
Muscle	Thienosaccharine + sulfonamide-carboxylic acid	Methyl carbamate, dimethyl carbamate, MMT	Sulfonamide	BYH 18636, triazolinone-carboxamide
Liver	Thienosaccharine + sulfonamide-carboxylic acid, sulfonamide	Methyl carbamate, MMT		BYH 18636, triazolinone-carboxamide

NATURE OF THE RESIDUE IN LACTATING GOAT			PMRA # 1410087, 1410088	
A lactating goat was orally dosed 5 times in 24 h intervals with 2.00 mg/kg bw/day [thiophene-4-14C]-BYH18636 (corresponding to 41.25 ppm in the daily diet) and sacrificed 24 hours after the last dose. A lactating goat was also orally dosed 5 times in 24 h intervals with 2.00 mg/kg bw/day [Dihydrotriazole-3-14C]-BYH18636 (corresponding to 41.34 ppm in the daily diet) and sacrificed 24 hours after the last dose. The milk, edible organs and tissues, excreta and urine were analysed for the parent and metabolites. Samples were extracted using acetonitrile/water and acetonitrile/water/acetic acid, and purified by solid phase extraction prior to analysis by HPLC-MS/MS.				
Matrices			% of Administered Dose	
			[Thiophene-4-14C]	[Dihydrotriazole-3-14C]
Urine and feces			43.84 and 46.95	35.61 and 45.28
Muscle			0.10	1.453
Fat			0.04	0.175
Kidney			0.01	0.026
Liver			0.84	0.264
Milk			0.15	1.92
Metabolites identified	Major Metabolites (> 10% TRR)		Minor Metabolites (< 10% TRR)	
Radiolabel Position	[Thiophene-4-14C]	[Dihydrotriazole-3-14C]	[Thiophene-4-14C]	[Dihydrotriazole-3-14C]
Milk	BYH 18636	Methyl carbamate, MMT	Thienosaccharine, sulfonamide-carboxylic acid, sulfonamide	OMT, BYH 18636,
Muscle	BYH 18636, sulfonamide	Methyl carbamate, MMT	sulfonamide-carboxylic acid	Triazoledione, OMT
Fat	sulfonamide-carboxylic acid	Methyl carbamate, MMT	BYH 18636, Thienosaccharine, sulfonamide	Triazoledione
Liver	sulfonamide	Methyl carbamate, Triazoledione, MMT	sulfonamide-carboxylic acid	OMT
Kidney	sulfonamide-carboxylic acid, sulfonamide	Methyl carbamate, MMT	BYH 18636	Triazoledione


Proposed Metabolic Scheme in Animals (goat, hen and rat)
BYH18636
N-desmethyl
(h,g)
carboxylic acid
(r,h,g)
triazolinone-carboxamide
(h)
sulfonamide
(r*,h,g)
MMT
(r,h,g)
sulfonamide-carboxylic acid
(r,h,g)
triazoldione
(g)
OMT
(r,g)
dimethyl carbamate
(h)
thienosaccharine
(r,h,g)
methyl carbamate
(r,h,g)
CO2
(r) = rat
(h) = hen
(g) = goat

STORAGE STABILITY PLANTS AND ANIMALS	PMRA # 1410075, 1410076

Samples of corn kernel and stover (dry/cereal), corn forage (high water), soybean (oily, protein-containing crop), lettuce (high-water crop), potato (starchy root crop) and tomato (acidic, fruiting vegetable) were spiked separately with 224 – 286 µg/kg of each thiencarbazone-methyl (BYH18636) and the metabolites BYH18636-N-desmethyl (M07) and BYH18636-MMT-glucoside (M22) and stored at ≤ -18ºC for up to 12 months. Spiked samples were analysed at nominal intervals of 0, 30, 90, 180 and 360 days. All samples were analysed using the validated HPLC-MS/MS method 00963. Residues of BYH18636 and the metabolites BYH18636-N-desmethyl (M07) and BYH18636-MMT-glucoside (M22) were shown to be stable during frozen storage at ≤ -18ºC for up to 12 months in all matrices investigated. The applicant has indicated that the storage stability study conducted on plants is an interim study and that a further storage interval of 18 months will be captured as part of the final study. As a requirement of registration the final storage stability study will be required.

All tissue and milk samples were analyzed for BYH 18636, BYH 18636-MMT and BYH 18636-methyl carbamate; and liver, kidney, and muscle samples were analyzed for BYH 18636-sulfonamide within 23 days of collection; therefore, freezer storage stability data were not required for these analytes and matrices. Milk and fat samples were analyzed for BYH 18636-sulfonamide within 46 days of collection, therefore storage stability data are presented for a storage period of 2 months. The storage stability experiment showed that BYH 18636-sulfonamide residues were stable in milk and fat for at least 2 months when stored at ≤18 °C.

CROP FIELD TRIALS ON CORN	PMRA # 1410089, 1410090, 1410097, 1410098

GAP: Maximum seasonal rate of 7.5 g a.i./ha at the 6 leaf stage (latest)

Thirty field trials in the appropriate NAFTA representative growing regions were completed to investigate the magnitude of total BYH 18636 (thiencarbazone-methyl) residues in/on sweet corn, field corn, and pop corn. Crops were treated with one of four application patterns at a target rate of 45 g a.i./ha/season. Two plots received a pre-plant application the third plot received the first application at the V2 (second leaf collar) stage. The second application for all three plots was made at the V6 (sixth leaf collar) stage. A fourth plot was treated with three applications at the V2, V6 and V8 (eight leaf collar).

Residues of thiencarbazone-methyl were measured using the Bayer HPLC-MS/MS Method 00963. The total residues of thiencarbazone-methyl in/on field corn grain, sweet corn ears and popcorn grain were < LOQ (0.01 ppm). No differences in resulting residues were noted with different formulations (WDG versus FlC).

Crop matrix	Total Applic. Rate (lb ai/A) [kg ai/ha]	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median	Mean	Std. Dev.
Field Corn									
Field corn forage 45-day PHI	0.039-0.042 (0.044-0.047)	42-58	23	<0.010	<0.010	0.010	0.010	0.010	NA
Field corn forage BBCH 85-87		59-115	21	<0.010	<0.010	0.010	0.010	0.010	NA
Field corn forage 45-day PHI	0.039-0.042 (0.044-0.047)	42-58	23	<0.010	<0.010	0.010	0.010	0.010	NA

Crop matrix	Total Applic. Rate (lb ai/A) [kg ai/ha]	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median	Mean	Std. Dev.
Field corn forage BBCH 85-87	0.039-0.043 (0.044-0.048)	59-115	21	<0.010	<0.010	0.010	0.010	0.010	NA
Field corn forage 45-day PHI		42-58	46	<0.010	<0.010	0.010	0.010	0.010	NA
Field corn forage BBCH 85-87		59-115	42	<0.010	0.016	0.015	0.010	0.010	0.001
Field corn forage 45-day PHI	0.039-0.042 (0.044-0.047)	42-50	41	<0.010	<0.010	0.010	0.010	0.010	NA
Field corn forage BBCH 85-87		52-107	39	<0.010	0.037	0.024	0.010	0.011	0.004
Field corn grain	0.039-0.042 (0.044-0.047)	87-129	23	<0.010	<0.010	0.010	0.010	0.010	NA
Field corn grain	0.039-0.042 (0.044-0.047)	87-129	23	<0.010	<0.010	0.010	0.010	0.010	NA
Field corn grain	0.039-0.043 (0.044-0.048)	87-129	46	<0.010	<0.010	0.010	0.010	0.010	NA
Field corn grain	0.039-0.042 (0.044-0.047)	82-121	44	<0.010	<0.010	0.010	0.010	0.010	NA
Field corn stover	0.039-0.042 (0.044-0.047)	87-129	23	<0.010	<0.010	0.010	0.010	0.010	NA
Field corn stover	0.039-0.042 (0.044-0.047)	87-129	23	<0.010	0.014	0.014	0.010	0.010	0.001
Field corn stover	0.039-0.043 (0.044-0.048)	87-129	46	<0.010	0.013	0.012	0.010	0.010	0.000
Field corn stover	0.039-0.042 (0.044-0.047)	88-121	44	<0.010	0.016	0.016	0.010	0.010	0.001

Crop matrix	Total Applic. Rate (lb ai/A) [kg ai/ha]	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median	Mean	Std. Dev.
Sweet Corn									
Sweet corn forage 45-day PHI	0.039-0.041 (0.044-0.046)	42-58	15	<0.010	<0.010	0.010	0.010	0.010	NA
Sweet corn forage BBCH 73-79		28-76	13	<0.010	0.015	0.015	0.010	0.010	0.002
Sweet corn forage 45-day PHI	0.039-0.041 (0.044-0.046)	42-58	15	<0.010	<0.010	0.010	0.010	0.010	NA
Sweet corn forage BBCH 73-79		28-76	13	<0.010	0.012	0.012	0.010	0.010	0.001
Sweet corn forage 45-day PHI	0.039-0.043 (0.044-0.048)	42-58	30	<0.010	0.021	0.018	0.010	0.010	0.002
Sweet corn forage BBCH 73-79		28-76	26	<0.010	0.029	0.025	0.010	0.012	0.004
Sweet corn forage 45-day PHI	0.039-0.042 (0.044-0.047)	43-45	28	<0.010	0.047	0.040	0.010	0.012	0.007
Sweet corn forage BBCH 73-79		21-63	26	<0.010	0.160	0.126	0.010	0.019	0.031
Sweet corn ears 45-day PHI	0.039-0.041 (0.044-0.046)	42-58	15	<0.010	<0.010	0.010	0.010	0.010	NA
Sweet corn ears BBCH 73-79		28-76	13	<0.010	<0.010	0.010	0.010	0.010	NA
Sweet corn ears 45-day PHI	0.039-0.041 (0.044-0.046)	42-58	15	<0.010	<0.010	0.010	0.010	0.010	NA
Sweet corn ears BBCH 73-79		28-76	13	<0.010	<0.010	0.010	0.010	0.010	NA
Sweet corn ears 45-day PHI	0.039-0.043 (0.044-0.048)	42-58	30	<0.010	<0.010	0.010	0.010	0.010	NA

Crop matrix	Total Applic. Rate (lb ai/A) [kg ai/ha]	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median	Mean	Std. Dev.
Sweet corn ears BBCH 73-79	0.039-0.042 (0.044-0.047)	28-76	26	<0.010	<0.010	0.010	0.010	0.010	NA
Sweet corn ears 45-day PHI		43-45	28	<0.010	<0.010	0.010	0.010	0.010	NA
Sweet corn ears BBCH 73-79		21-63	26	<0.010	<0.010	0.010	0.010	0.010	NA
Sweet corn stover	0.039-0.041 (0.044-0.046)	63-129	15	<0.010	0.023	0.023	0.010	0.011	0.002
Sweet corn stover	0.039-0.041 (0.044-0.046)	63-129	15	<0.010	<0.010	0.010	0.010	0.010	NA
Sweet corn stover	0.039-0.043 (0.044-0.048)	63-129	30	<0.010	0.024	0.022	0.010	0.010	0.003
Sweet corn stover	0.039-0.042 (0.044-0.047)	56-121	28	<0.010	0.042	0.034	0.010	0.011	0.006
Popcorn									
Popcorn grain	0.039-0.040 (0.044-0.045)	99-116	3	<0.010	<0.010	0.010	0.010	0.010	NA
Popcorn grain	0.040-0.041 (0.045-0.046)	99-116	3	<0.010	<0.010	0.010	0.010	0.010	NA
Popcorn grain	0.040 (0.045)	91-108	6	<0.010	<0.010	0.010	0.010	0.010	NA
Popcorn grain	0.040-0.041 (0.045-0.046)	99-116	6	<0.010	<0.010	0.010	0.010	0.010	NA
Popcorn stover	0.039-0.040 (0.044-0.045)	99-116	3	<0.010	<0.010	0.010	0.010	0.010	NA
Popcorn stover	0.040-0.041 (0.045-0.046)	99-116	3	<0.010	<0.010	0.010	0.010	0.010	NA

Crop matrix	Total Applic. Rate (lb ai/A) [kg ai/ha]	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median	Mean	Std. Dev.
Popcorn stover	0.040 (0.045)	99-116	6	<0.010	<0.010	0.010	0.010	0.010	NA
Popcorn stover	0.040-0.041 (0.045-0.046)	91-108	6	<0.010	<0.010	0.010	0.010	0.010	NA

CROP FIELD TRIALS ON WHEAT	**PMRA # 1410101, 1410102**

GAP: Maximum seasonal rate of 5 g a.i./ha

Twenty three trials were conducted in the representative NAFTA growing regions. Two application patterns were tested at each trial site using a total target rate of 5 g a.i./ha/season. Wheat received either a single application at the one leaf unfolded to two tillers stage or a single application at the three tillers detectable to beginning of stem elongation stage. Residues of thiencarbazone-methyl were measured with the Bayer HPLC-MS/MS method 00962. The residues of thiencarbazone-methyl in/on wheat grain as a result of treatment at 5 g a.i./ha/season were all < LOQ (0.01 ppm).

Commodity	Total Applic. Rate lb a.i./A (kg a.i./ha)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMR)	Mean	Std. Dev.
Wheat forage	0.0043-0.0047 (0.0048-0.0053)	5-7	46	<0.010	0.070	0.065	0.010	0.014	0.013
Wheat hay	0.0044-0.0047 (0.0049-0.0053)	30-32	46	<0.01	<0.01	0.01	0.01	0.01	NA
Wheat straw	0.0044-0.0047 (0.0049-0.0053)	58-67	46	<0.01	<0.01	0.01	0.01	0.01	NA
Wheat grain	0.0044-0.0047 (0.0049-0.0053)	58-67	46	<0.01	<0.01	0.01	0.01	0.01	NA

Field Accumulation in Rotational Crops	**PMRA # 1410113, 1410114, 1410115**

CROP FIELD TRIALS ON WHEAT	PMRA # 1410101, 1410102
GAP: Maximum seasonal rate of 5 g a.i./ha	
Twenty soybean trials were conducted with a plantback interval (PBI) of 2 months, three soybean trials were conducted with a PBI of nine and twelve months. A single broadcast application of the 21% WDG formulation was made to bare soil or to corn (post-emergent) at a target rate of 0.45 kg a.i./ha two months, nine months or twelve months before planting soybeans. At the appropriate time the corn crop was destroyed by tillage to prepare for planting the soybean crop. Soybean samples were harvested at BBCH 19 to 69 (forage), BBCH 65 to 75 (hay) and at commercial maturity (BBCH 89) for seed. Residues of thiencarbazone-methyl and BYH 18636-MMT-glucoside were measured using the Bayer HPLC-MS/MS method 00963. Residues of thiencarbazone-methyl in/on seeds were < LOQ (0.01 ppm), in/on forage <0.031 ppm and in/on hay <0.083 ppm. A Maximum Residue Limit (MRL) for soybean seeds, as a rotated crop, is not required. Twenty wheat trials were conducted with a PBI of 3 months. A single broadcast application of the 21% WDG formulation was made to corn (post-emergent) at a target rate of 0.45 kg a.i./ha three months before planting wheat. Between 81 and 90 days the corn crop was destroyed by tillage to prepare for planting the wheat crop. Residues of thiencarbazone-methyl and BYH 18636-MMT-glucoside were measured using the Bayer HPLC-MS/MS method 00963. Residues of thiencarbazone-methyl in/on wheat grain, forage, hay and straw were < LOQ (0.01 ppm). An MRL for wheat grain, as a rotated crop, is not required.	

Commodity	Total Applic. Rate lb a.i./A (kg a.i./ha)	PBI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMR)	Mean	Std. Dev.
ROTATED SOYBEANS (planted after single broadcast application of 21% WDG formulation to bare soil or a target crop of corn)									
Soybean, forage	0.040-0.042 (0.045-0.047)	50-61	40	<0.02	<0.031	0.031	0.020	0.022	0.003
Soybean, hay	0.040-0.042 (0.045-0.047)		40	<0.02	<0.083	0.067	0.024	0.034	0.022
Soybean, seed	0.040-0.042 (0.045-0.047)		40	<0.01	<0.01	0.01	0.01	0.01	NA
Soybean, forage	0.040 (0.045)	265-288	6	<0.020	<0.020	0.020	0.020	0.020	NA
Soybean, hay	0.040 (0.045)		6	<0.023	<0.030	0.030	0.025	0.026	0.003
Soybean, seed	0.040 (0.045)		6	<0.010	<0.010	0.010	0.010	0.010	NA
Soybean, forage	0.040 (0.045)	356-363	6	<0.020	<0.020	0.020	0.020	0.020	NA

Commodity	Total Applic. Rate lb a.i./A (kg a.i./ha)	PBI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMR)	Mean	Std. Dev.
Soybean, hay	0.040 (0.045)		6	<0.020	<0.027	0.024	0.022	0.022	0.002
Soybean, seed	0.040 (0.045)		6	<0.010	<0.010	0.010	0.010	0.010	NA
ROTATED WHEAT (planted after single broadcast application of 21% WDG formulation to bare soil or a target crop of corn)									
Wheat, forage	0.038-0.042 (0.043-0.047)	81-90	40	<0.010	<0.010	0.010	0.010	0.010	NA
Wheat, hay	0.038-0.042 (0.043-0.047)	81-88	10	<0.010	<0.010	0.010	0.010	0.010	NA
Wheat, grain	0.038-0.042 (0.043-0.047)	81-89	14	<0.010	<0.010	0.010	0.010	0.010	NA
Wheat, straw	0.038-0.042 (0.043-0.047)	81-89	14	<0.010	<0.010	0.010	0.010	0.010	NA
PROCESSED FOOD AND FEED							**PMRA # 1410103, 1410104, 1410106, 1410105**		

Commodity	Total Applic. Rate lb a.i./A (kg a.i./ha)	PBI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMR)	Mean	Std. Dev.

Field trials were conducted on corn, wheat (as a primary crop and a secondary crop) and soybean (as a secondary crop) in order to evaluate the need for residue analyses on processed commodities. Corn was treated three times using a broadcast foliar application (21% WDG formulation) of 45 g a.i./ha/application (total 135 g a.i./ha/season; 18-fold the proposed use rate). Samples were analyzed for thiencarbazone-methyl and the BYH 18636-MMT-glucoside and BYH 18636-N-desmethyl metabolites using the HPLC-MS/MS Bayer Method 00963. Due to residues in/on corn grain samples <LOQ (0.01 ppm), the generation of corn processed commodities was not conducted.

Wheat was treated, as a primary crop, with a single post-emergent application of thiencarbazone-methyl (OD 70 formulation) at a target rate of 25 g a.i./ha/season (fivefold the proposed use rate) and harvested at 59-day PHI. Residues of thiencarbazone-methyl and the BYH 18636-MMT-glucoside and BYH 18636-N-desmethyl metabolites in/on wheat grain samples were determined using the HPLC-MS/MS Bayer Method 00962. Due to residues in/on wheat grain samples <LOQ (0.01 ppm), the generation of wheat processed commodities (bran, flour, middlings, shorts and germ) was not conducted.

Rotational crops (wheat and soybean) were also analyzed for residues of thiencarbazone-methyl in order to evaluate the need for residue analyses on processed commodities. In both trials the soil was treated with 135 g a.i./ha and soybean and wheat were planted at 49 days and 82 days, respectively, following the application. Commodities were harvested at normal commercial harvest. Residues of thiencarbazone-methyl and the BYH 18636-MMT-glucoside and BYH 18636-N-desmethyl metabolites in/on wheat grain and soybean seed were measured using the HPLC-MS/MS Bayer Method 00963. Results indicated that the residues were < LOQ (0.01 ppm) for each analyte measured. Therefore, generation of processed commodities was not conducted.

LIVESTOCK FEEDING – Dairy cattle | **PMRA # 1410076**

Eleven lactating Holstein dairy cows (Bos taurus; three cows/treatment group and two control cows) were dosed orally with thiencarbazone-methyl for 29 consecutive days via capsule. The target dose rates were (based on feed dry weight) 0 mg/kg feed/day (control), 0.4 mg/kg feed/day, 1.2 mg/kg feed/day or 4.0 mg/kg feed/day. Milk was collected twice daily. Daily composited samples were analyzed for parent along with the BYH 18636-MMT (M21) and BYH 18636-methyl carbamate (M23) metabolites. From the highest dose level the metabolite BYH 18636-sulfonamide (M15) was also measured. Cows were sacrificed within 12-18 hours of the final dose on study day 29 to yield samples of liver, kidney, composite muscle, subcutaneous fat, omental fat, and perirenal fat.

Total residues of thiencarbazone-methyl and BYH 18636-MMT in Dairy cattle.

Matrix	Feeding Level (ppm/d)	n	LOQ	Min	Max	Median	Mean	Standard Deviation
Milk	0.4	27	0.02	0.02	0.02	-	-	-
Liver		3	0.02	0.02	0.04	0.02	0.03	0.01
Kidney		3	0.02	0.02	0.02	-	-	-
Muscle		3	0.02	0.02	0.02	-	-	-
Fat		Not measured						
Milk	1.2	27	0.02	0.02	0.03	0.01	-	-
Liver		3	0.02	0.04	0.07	0.04	0.05	0.02

Commodity	Total Applic. Rate lb a.i./A (kg a.i./ha)	PBI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMR)	Mean	Std. Dev.
Kidney		3	0.02	0.02	0.03	0.03	0.03	0.006	
Muscle		3	0.02	0.02	0.03	0.02	0.02	0.006	
Fat		3	0.02	0.02	0.02	-	-	-	
Milk		27	0.02	0.03	0.06	0.05	0.05	0.006	
Liver		3	0.02	0.11	0.15	0.12	0.13	0.02	
Kidney	4.0	3	0.02	0.07	0.11	0.07	0.08	0.02	
Muscle		3	0.02	0.05	0.06	0.05	0.05	0.006	
Fat		3	0.02	0.02	0.02	-	-	-	

Calculation of Livestock Maximum Theoretical Dietary Burden in Beef, Dairy, Poultry and Swine

The potential for transfer of total thiencarbazone-methyl residues in meat and milk exists because there are livestock feedstuffs associated with the proposed uses on corn and wheat. The calculated MTDB, based on Canadian MRLs for field corn grain and wheat grain and the U.S tolerances for feed items is 0.134 ppm for beef cattle, 0.176 ppm for dairy cattle and 0.008 ppm for both poultry and swine.

				% Diet				Maximum Theoretical Dietary Burden (ppm)			
Feedstuff	Type	MRL (ppm)	% DM	Beef	Dairy	Poultry	Swine	Beef	Dairy	Poultry	Swine
Wheat forage	R	0.1	25	25	40	-		0.1	0.160	-	-
Soybean hay	R	0.15	85	15	5	-		0.026	0.009	-	-
Peanut meal	P	0.000	85	15	15	-		0.000	0.000	-	-
Corn, field, milled by products	C	0.01	85	35	25	-		0.004	0.003	-	-
Corn, sweet, cannery waste	C	0.01	30	10	10	-		0.003	0.003	-	-
Corn, pop, grain	C	0.01	88	-	5	70		-	0.001	0.007	-
Alfalfa meal	P	0.000	10	-	-	10	10	-	-	0.000	0.000
Rape meal	P	0.000	10	-	-	10	10	-	-	0.000	0.000
Corn, field, grain	C	0.01	-	-	-	-	80	-	-	-	0.008

Commodity	Total Applic. Rate lb a.i./A (kg a.i./ha)		PBI (days)	Residue Levels (ppm)							
				n	Min.	Max.	HAFT	Median (STMR)	Mean	Std. Dev.	
Wheat grain	C	0.01	10	-	-	10	-	-	-	0.001	-
Totals				100	100	100	100	0.134	0.176	0.008	0.008

R (roughage); C (carbohydrates); P (protein)

Calculation of the Anticipated Residues for Dietary Exposure Assessment

Commodity	Feeding level (ppm)	Maximum Residues (ppm)	Transfer Coefficient * (ppm)	MTDB1 (ppm)		Anticipated Residue (ppm)	
				Dairy	Hog	Beef/Dairy	Hog2
Milk	0.4	0.02	0.05	0.176	0.01	0.0088	-
Fat	1.2	0.02	0.02	0.176	0.01	0.00352	-
Kidney	0.4	0.02	0.05	0.176	0.01	0.0088	-
Liver	0.4	0.02	0.05	0.176	0.01	0.0088	-
Muscle	0.4	0.02	0.05	0.176	0.01	0.0088	-

1 Maximum Theoretical Dietary Burden
2 no expectation of measurable residues in hog commodities.
* Transfer coefficient = Maximum residues/feeding level

LIVESTOCK FEEDING – Laying hens | **PMRA # none**

Given the residue levels in the hen metabolism studies and that there were no measurable residues in wheat and corn grain commodities in the magnitude of the residue trials, a hen feeding study was not conducted. The MTDB for poultry commodities was calculated using values from the metabolism studies.

Commodity	Feeding level (ppm)	Maximum residues (ppm)	Transfer Coefficient* (ppm)	MTDB1 (ppm)	Anticipated residue2 (ppm)
Muscle	27.16	0.056	0.002	0.01	-
Fat	27.16	0.008	0.0002	0.01	-
Liver	27.16	0.095	0.003	0.01	-
Eggs	27.16	0.115	0.004	0.01	-

1 Maximum Theoretical Dietary Burden
2 no expectation of measurable residues in hog commodities.
* Transfer coefficient = Maximum residues/feeding level

Table 6 Food Residue Chemistry Overview of Metabolism Studies and Risk Assessment

PLANT STUDIES		
RESIDUE DEFINITION FOR ENFORCEMENT **Primary crops (corn)** **Rotational crops**		Thiencarbazone-methyl Thiencarbazone-methyl
RESIDUE DEFINITION FOR RISK ASSESSMENT **Primary crops** **Rotational crops**		Thiencarbazone-methyl Thiencarbazone-methyl
METABOLIC PROFILE IN DIVERSE CROPS		The profile in diverse crops cannot be determined, because only corn and wheat were investigated.
ANIMAL STUDIES		
ANIMALS		**Ruminant**
RESIDUE DEFINITION FOR ENFORCEMENT		Thiencarbazone-methyl and BYH 18636-MMT
RESIDUE DEFINITION FOR RISK ASSESSMENT		Thiencarbazone-methyl
METABOLIC PROFILE IN ANIMALS **(goat, hen, rat)**		Is the profile similar in animals investigated? Yes
FAT SOLUBLE RESIDUE		No
DIETARY RISK FROM FOOD AND WATER		
	POPULATION	**ESTIMATED RISK % of ACCEPTABLE DAILY INTAKE (ADI)**
		Food Only / **Food and Water**
Refined chronic non-cancer dietary risk **ADI = 1.17 mg/kg bw** **Estimated chronic drinking water concentration = 1.9 □g/L**	**All infants < 1 year**	0.0 / 0.0
	Children 1–2 years	0.1 / 0.1
	Children 3 to 5 years	0.1 / 0.1
	Children 6–12 years	0.0 / 0.0
	Youth 13–19 years	0.0 / 0.0
	Adults 20–49 years	0.0 / 0.0
	Adults 50+ years	0.0 / 0.0
	Total population	0.0 / 0.0

Table 7 Fate and Behaviour of Thiencarbazone-methyl (TCM) and its Transformation Products in the Terrestrial Environment

Property	Test substance	Value	Comments	Reference
Abiotic transformation				
Phototransformation on soil	TCM	stable	Not an important route of transformation	1410119
Phototransformation in air	-	-	not required – non-volatile	1409955
Biotransformation				
Biotransformation in aerobic soil	TCM	half-life: 36 days	Important route of transformation slightly persistent	1410116 1410117
Biotransformation in anaerobic soil	TCM	half-life: 108 days	Not an important route of transformation moderately persistent	1410118
Mobility				
Adsorption / desorption in soil	TCM	Koc: 59.9 – 236	moderately to highly mobile, sorption correlates to soil organic matter	1410133
	BYH 18636-carboxylic acid	Koc: 4.81 – 32.5	very highly mobile	1410138
	BYH 18636-MMT	Koc: 4.44 – 39.6	very highly mobile	1410135
	BYH 18636-sulfonamide	Koc: 130 - 299	moderately to highly mobile	1410137
	BYH 18636-sulfonamide-carboxylic acid	Koc: 2.94 – 87.8	high to very highly mobile	1410136
	BYH18636-triazolinone carboxamide	Koc: 18	estimated using HPLC analysis, very highly mobile	1410134
Volatilization	-	-	non-volatile	
Field studies				
Field dissipation	TCM	half-life: 17.5 – 44.5 days	slightly persistent potential to leach and contaminate groundwater	1410127 1410128 1410131

Property	Test substance	Value	Comments	Reference
	BYH18636-carboxylic acid	-	High potential to leach and contaminate groundwater Maximum %AR reached at study termination in the silt loam soil (Swift Current, SK) in the 0 - 7.5 cm depth	1410127 1410128 1410131
	BYH18636-sulfonamide	-	High potential to leach and contaminate groundwater residues peaked by 21 days at 0 – 7.5 cm depth	1410127 1410128 1410131
	BYH18636-MMT	-	High potential to leach and contaminate groundwater residues peaked by 15 days at 0 – 7.5 cm depth	1410127 1410128 1410131

Table 8 Fate and Behaviour of Thiencarbazone-methyl (TCM) and its Transformation Products in the Aquatic Environment

Property	Test material	Value	Comments	Reference
Abiotic transformation				
Hydrolysis	TCM	Half-lives: pH 4: 50 days pH 7: 148 days pH 9: 154 days	not an important route of transformation slightly to moderately persistent, dependant upon pH	1409986
Phototransformation in water	TCM	stable	not an important route of transformation	1409987
Biotransformation				
Biotransformation in aerobic water systems	TCM	Half-lives: 18.1 (sandy loam) 28 days (loamy sand)	Principle route of transformation slightly persistent	1410150
Biotransformation in anaerobic water systems	TCM	half-life: 7.6 days	Principle route of transformation non-persistent	1410147
Field studies				
Water	BYH18636-carboxylic acid	DT_{50}s: 79.5 – 138.5	non-persistent to moderately persistent	1410127 1410128 1410131

Property	Test material	Value	Comments	Reference
Sediment	BYH18636-carboxylic acid	DT_{50}s: 62.9 – 88.3	slightly to moderately persistent	1410147
Water	BYH18636-MMT	DT_{50}s: 98 - 119	moderately persistent	1410149

Table 9 Effects on Terrestrial Organisms

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[a]	References
Invertebrates					
Earthworm (*Eisenia fetida*)	Acute	TCM	LC_{50}>1000 mg/kgdw soil		1410216
	Acute	BYH18636-carboxylic acid	LC_{50}>1000 mg/kgdw soil		1410215
	Reproductive (56 days)	SC450 formulation	NOEC≥ 10 L SC450/ha equivalent to NOEC≥176.4 g a.i./ha		1410221
	Reproductive	BYH18636-carboxylic acid	NOEC>1000 mg/kgdw soil		1410220
	Reproductive	BYH18636-sulfonamide	NOEC = 654 mg/kg dry weight soil		1410219
	Reproductive	BYH18636-sulfonamide-carboxylic acid	NOEC>1000 mg/kgdw soil		1410218
	Reproductive	BYH18636-MMT	NOEC=855 mg/kg dry weight soil		1410217
	Reproductive (14 days)	SC450 formulation	NOEC> 1000 mg SC450/kg dw soil equivalent to NOEC>174 mg a.i./kg dw soil		1410221
Folsomia candida (Collembola)	Chronic: reproductive	TCM	NOEC>1000 mg/kg dry soil		1410183
	Chronic: reproductive	BYH18636-carboxylic acid	NOEC>1000 mg/kg dry soil		1410182

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[a]	References
	Chronic: reproductive	BYH18636-sulfonamide-carboxylic acid	NOEC>1000 mg/kg dry soil		1410181
	Chronic: reproductive	BYH18636-MMT	NOEC>1000 mg/kg dry soil		1410180
	Chronic: reproductive	BYH18636-trazolinone carboxamide	NOEC>1000 mg/kg dry soil		1410179
Bee (*Apis mellifera*)	Oral	TCM	LD_{50}>199 g/bee	relatively non-toxic	1410212
	Contact	TCM	LD_{50}>200 g/bee	relatively non-toxic	1410212
Predatory arthropod (*Typhlodromus pyri*)	Contact	SC 450 (BYH 18636: 19.1%w/w)	LR50>200 mL/ha (mortality) NOER>200 mL/ha (reproductive)	harmless	1410214
Parasitic arthropod (*Aphidius rhopalosiphi*)	Contact	SC 450 (BYH 18636: 19.1%w/w)	LR50>200 mL/ha (mortality) NOER: 36 mL/ha (reproductive)	harmless	1410215
Birds					
Bobwhite quail *(Colinus virginianus)*	Acute	TCM	LD_{50}> 2000 mg/kg bw	practically non-toxic	1410151
	Dietary	TCM	LC_{50}>699 mg/kg bw/day or LC50>3847 mg/kg diet	moderately toxic	1410152
	Reproduction	TCM	NOEL= 61 mg/kg bw/day or 633 mg/kg diet		1410155
Mallard duck *(Anas platyrhynchos)*	Acute	-	-	-	
	Dietary	TCM	LC_{50}>832 mg/kg bw/day or 3847 mg/kg diet	moderately toxic	1410153
	Reproduction	TCM	NOEL=24 mg/kg bw/day or 204 mg/kg diet		1410154

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[a]	References
Mammals					
Rat	Acute	TCM	LD50 > 2000 mg/kg bw		1410036
	Dietary	TCM	NOAEL:123/154 mg/kg bw/day (m/f)		1410044
	Reproduction	TCM	Parental NOAEL: 245/56 mg/kg bw/day (m/f)		1410057
	Acute	BYH18636-carboxylic acid	LD_{50} > 2000 mg/kg bw		1410071
	Dietary	BYH18636-carboxylic acid	NOAEL: 972/1170 mg/kg bw/day (m/f)		1410070
	Acute	BYH18636-sulfonamide	LD_{50} > 2000 mg/kg bw		1410031
	Dietary	BYH18636-sulfonamide	NOAEL: 800/917 mg/kg bw/day (m/f)		1410067
Mouse	Dietary	TCM	NOAEL: 315 mg/kg bw/day (m);789 mg/kg bw/day (f)		1410043
Rabbit	Reproduction	TCM	Maternal NOAEL: 125 mg/kg bw/day		1410059
Vascular plants					
Vascular plant	Seedling emergence	OD70 (10 g/L TCM)	ER25Ryegrass: 0.468 g a.i./ha		1501023
	Vegetative vigour	OD70 (10 g/L TCM)	ER25 Sunflower: 0.123 g a.i./ha		1501025
	pre-emergence	BYH18636-carboxylic acid	unreliable		1410170

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[a]	References
	post emergence	TCM and BYH18636-carboxylic acid	unreliable		1410169
[a]Atkins et al. (1981) for bees and US EPA classification for others, where applicable					

Table 10 Effects on Aquatic Organisms

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[a]	Reference
Freshwater species					
Daphnia magna	Acute	TCM	EC_{50}>98.6 mg a.i./L (measured dose, >100 g a.i./L nominal)	practically non-toxic	1410193
	Chronic	TCM	NOEL = 3.54 mg ai./L		1410194
	Acute	BYH18636-sulfonamide	EC_{50}: 100 mg a.i./L	practically non-toxic	1410192
Chironomus riparius larvae	Acute	TCM	EC_{50} >100 mg a.i./L	practically non-toxic	1410202
	Acute	BYH18636-carboxylic acid	EC_{50} >100 mg a.i./L	practically non-toxic	1410201
	Acute	BYH18636-sulfonamide-carboxylic acid	EC_{50} >100 mg a.i./L	practically non-toxic	1410200
Rainbow trout *(Oncorhynchus mykiss)*	Acute	TCM	EC_{50} >104 mg a.i./L	practically non-toxic	1410187
	Acute	BYH18636-sulfonamide	EC_{50} >98.3 mg a.i./L	practically non-toxic	1410186
Bluegill Sunfish *(Lepomis macrochirus)*	Acute	TCM	EC_{50} >107 mg a.i./L	practically non-toxic	1410188
Fathead Minnow (*Pimephales promelas*)	Chronic early life stage, 35 days	TCM	NOEL = 4.8 mg a.i./L		1410189
Green algae *(Pseudokirchneriella subcapitata)*	Acute	TCM	EC_{50}: 0.170 mg a.i./L		1410197

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[a]	Reference
Green algae *(Pseudokirchneriella subcapitata)*	Acute	BYH18636-sulfonamide	EC_{50}: 0.499 mg a.i./L		1410198
Freshwater diatom *(Navicula pelliculosa)*	Acute	TCM	EC_{50}: 59.3 mg a.i./L		1410196
Blue green algae *(Anabaena flos-aquae)*	Acute	TCM	EC_{50}: 4.25 mg a.i./L		1410195
Vascular plants	*Lemna gibba*	TCM	LC_{50}:0.0008 mg a.i./L NOEL: 0.0021 mg a.i./L		1410211
	Lemna gibba	TCM	LC_{50}: 0.00096 mg a.i./L 7-d EC_{25}: 0.00048 mg a.i./L		1410210
	Myriophyllum spicatum	TCM	LC_{50}: 0.00061 mg a.i./L 7-d EC_{25}: 0.00087 mg a.i./L 14-d EC_{25}: 0.00034 mg a.i./L		1410209
	Potamogeton pectinatus (sago pondweed) *Elodea canadensis* (Elodea) *Mentha aquatica* (Water Mint)	TCM	LC_{50}: 0.00053 mg a.i./L 7-d EC_{25}: 0.0008 mg a.i./L for sago pond weed only results inconclusive for other species tested		1410208
	Lemna gibba	BYH18636-carboxylic acid	LC_{50}: 2.08 mg a.i./L		1410207
	Lemna gibba	BYH18636-sulfonamide-carboxylic acid	LC_{50}: >100 mg a.i./L		1410206
	Lemna gibba	BYH18636-sulfonamide	LC_{50}: 61.6 mg a.i./L		1410205

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[a]	Reference
	Lemna gibba	BYH18636-MMT	LC_{50} >95.7 mg a.i./L		1410204
	Lemna gibba	BYH18636-dicarboxylic sulfonamide	LC_{50} >104 mg a.i./L		1410203
	Over-spray *Lemna gibba*	SC450 formulation	LR_{50}: 0.00567 mg SC450/L equivalent to LC_{50}: 0.00099 mg a.i./L	endpoint based on frond area	1420377
Marine species					
Crustacean (*Americamysis bahia*)	Acute	TCM	LC_{50}>94 mg a.i./L	practically non-toxic	1410165
	Chronic – life cycle	TCM	NOEC >83 mg ai.i./L		1410164
Mollusk (*Crassostrea virginica*)	Acute	TCM	LC_{50} >100 mg a.i./L	practically non-toxic	1410166
Sheepshead minnow (*Cyprinodon variegatus*)	Acute	TCM	LC_{50} >106 mg a.i./L	practically non-toxic	1410167
Marine alga (*Skeletonema costatum*)	Acute	TCM	LC_{50} >114 mg a.i./L		1410163
[a]US EPA classification, where applicable					

Table 11 Risk to Terrestrial Organisms

Organism	Exposure	Endpoint value	EEC	Uncertainty Factor	Risk Quotient
Invertebrates					
Earthworm (*Eisenia fetida*)	Acute	LC_{50} >1000 mg a.i./kg dw soil	0.0033 mg a.i./kg	2	0.000007
Bee (*Apis mellifera*)	Oral	LD_{50} >199 ug/bee or 222 kg/ha	0.0075 kg a.i./ha	-	0.000034

Organism	Exposure	Endpoint value	EEC	Uncertainty Factor	Risk Quotient
	Contact	LD_{50} >200 ug/bee or 222 kg/ha	0.0075 kg a.i./ha	-	0.000034
Predatory arthropod (*Typhlodromus pyri*)	Contact	LR_{50}: 36 mL product/ha equivalent to 8.1 g a.i./ha	tests conducted with SC450 not proposed for use in Canada, used 7.5 g a.i./ha	-	0.9260
Parasitic arthropod (*Aphidius rhopalosiphi*)	Contact	LR_{50} >200 mL product/ha equivalent to 45 g a.i./ha	tests conducted with SC450 not proposed for use in Canada, used 7.5 g a.i./ha	-	0.1667
Birds					
Bobwhite quail *(Colinus virginianus)*	Acute	LD >2000 mg a.i./L	1.31 mg a.i./kg dw		0.0007
	Dietary	LC_{50} >3847 mg a.i./L	1.31 mg a.i./kg dw		0.0003
	Reproduction	NOEC 633 mg a.i./kg feed	1.31 mg a.i./kg dw		0.0021
Mallard duck *(Anas platyrhynchos)*	Dietary	LC >3847 mg a.i./L	0.25 mg a.i./kg dw		0.00006
	Reproduction	NOEC 204 mg a.i./kg feed	0.25 mg a.i./kg dw		0.0012
Mammals					
Rat	Acute	LD >2000 mg/kg bw	3.78 mg a.i./kg dw	-	0.0019
	Dietary	NOAEL 123 mg/kg bw/day for males	3.78 mg a.i./kg dw	-	0.0307
	Reproduction	NOEC: 56 mg a.i./kg bw/day parental females	3.78 mg a.i./kg dw	-	0.0675
Mouse	Dietary	NOAEL 315 mg/kg bw/day for males	3.76 mg a.i./kg dw	-	0.0119
Rabbit	Reproduction	NOAEL 125 mg a.i./kg bw/day maternal	5.66 mg a.i./kg dw	-	0.0453

Organism	Exposure	Endpoint value	EEC	Uncertainty Factor	Risk Quotient
Vascular plants					
Vascular plant	Seedling emergence	ER_{50} ryegrass: 0.862 g a.i./ha ER_{25}Ryegrass: 0.468 g a.i./ha	7.5 g a.i./ha		**16.03**
	Vegetative vigour	ER_{50} cucumber : 0.491 g a.i./ha ER25 Sunflower: 0.123 g a.i./ha	7.5 g a.i./ha		**60.98**

Table 12 Screening Level EECs: Direct Application for Highest Application Rate on Corn

Use-pattern	Terrestrial habitat EEC		Aquatic habitat		
	Maximum rate (g a.i./ha)	Soil (mg a.i./kg)	Maximum rate (g a.i./ha)	EEC (mg a.i./L)	
				[1]Amphibian habitat	[2]Wetland habitat
Corn field and sweet	7.5	0.0033	7.5	0.005	0.0009375

[1]Based on 0.15 m deep pond to represent seasonal breeding habitats for amphibians
[2]Based on 0.80 m deep pond to represent wetland habitats

Table 13 Surface Runoff: Aquatic Ecoscenario Modelling Results (µg/L) for Thiencarbazone-methyl (80 cm depth water body)

Region	EEC (µg ai/L)					
	Peak	96-hour	21-day	60-day	90-day	Yearly
Wheat, 1 x 5 g ai/ha						
Manitoba	0.087	0.083	0.071	0.047	0.037	0.0110
Saskatchewan	0.076	0.073	0.060	0.040	0.031	0.0098
Corn, 1 x 7.5 g ai/ha						
Ontario	0.227	0.218	0.189	0.130	0.102	0.0282
Québec	0.192	0.186	0.163	0.121	0.096	0.0275

Region	EEC (µg ai/L)					
	Peak	96-hour	21-day	60-day	90-day	Yearly
Atlantic	0.605	0.597	0.530	0.403	0.327	0.0972

Table 14 Maximum EECs in Vegetation and Insects After a Direct Overspray

Matrix	EEC fresh weight (mg ai/kg fw)[a]	Fresh / dry weight ratios	EEC dry weight (mg ai/kg dw)
Short range grass	1.605	3.3[b]	5.297
Leaves and leafy crops	0.840	11[b]	9.240
Long grass	0.735	4.4[b]	3.234
Forage crops	0.900	5.4[b]	4.860
Small insects	0.390	3.8[c]	1.482
Pods with seeds	0.080	3.9[c]	0.313
Large insects	0.067	3.8[c]	0.254
Grain and seeds	0.067	3.8[c]	0.254
Fruit	0.101	7.6[c]	0.764

[a]Based on correlations reported in Hoerger and Kenaga (1972) and Kenaga (1973)
[b]Fresh / dry weight ratios from Harris (1975)
[c]Fresh / dry weight ratios from Spector (1956)

Table 15 Maximum EECs in Diets of Birds and Mammals

Organism	Matrix	EEC (mg ai/kg dw diet)
Bobwhite quail *(Colinus virginianus)*	30% small insects 15% forage crops 55% grain	1.31
Mallard duck *(Anas platyrhynchos)*	30% large insects 70% grain	0.25
Rat	70% short grass 20% grain/seeds 10% large insects	3.78
Mouse	25% short grass 50% grain/seeds 25% leaves and leafy crops	3.76
Rabbit	25% short grass 25% leaves and leafy crops 25% long grass 25% forage crops	5.66

Table 16 Risks to Aquatic Organisms

Organism	Exposure	Endpoint value	EEC	[a]Correction factor	Risk Quotient
Freshwater species					
Daphnia magna	Acute	>98.6 mg a.i./L	0.0009375 mg a.i./L	2	1.90E-05
	Chronic	3.54 mg a.i./L	0.0009375 mg a.i./L	-	2.65E-04
Rainbow trout *(Oncorhynchus mykiss)*	Acute	>104 mg a.i./L	0.0009375 mg a.i./L	10	9.01E-05
Amphibians	Acute	[a]104 mg a.i./L	0.0009375 mg a.i./L	[b]10	9.01E-05
Bluegill Sunfish *(Lepomis macrochirus)*	Acute	>107 mg a.i./L	0.0009375 mg a.i./L	10	8.76E-05
Freshwater alga	Acute	0.170 mg a.i./L	0.0009375 mg a.i./L	2	1.10E-02

Organism	Exposure	Endpoint value	EEC	[a]Correction factor	Risk Quotient
Vascular plant	Dissolved	0.00034 mg a.i./L (*Myriophyllum spicatum*, 14 day EC25)	0.0009357 mg a.i./L	2	**5.51**
	Over-spray using SC450 formulation	0.00099 mg a.i./L	0.0009357 mg a.i./L	2	**1.89**
Marine species					
Crustacean (*Americamysis bahia*)	Acute	>94 mg a.i./L	0.0009375 mg a.i./L	2	1.99E-05
	Chronic	NOEC 11 mg a.i./L LC_{50}>83 mg a.i./L	0.0009375 mg a.i./L		8.52E-05
Mollusk (*Crassostrea virginica*)	Acute	>100 mg a.i./L	0.0009375 mg a.i./L	2	1.88E-05
Fathead minnow (*Pimephales promelas*)	Chronic early life cycle	NOEC 4.80 mg a.i./L (based on fry survival, day 35)	0.0009375 mg a.i./L		1.95E-04
Marine alga (*Skeletonema costatum*)	Acute	>114 mg a.i./L	0.0009375 mg a.i./L	2	1.64E-05

[a]Correction factors are used to account for the potential differences in species sensitivity as well as varying protection levels e.g. individual, community, population.

[b]for calculating risk to amphibians the most sensitive fish species endpoint was used as a surrogate value, in this case the LC50 for rainbow trout with an additional correction factor of 10 and the EEC for direct overspray into a 15 cm depth water body

Table 17 Risk to Aquatic Organisms: Tier 1 Surface Runoff

Organism	Exposure	Endpoint value	[1]EEC	[2]Correction factor	Risk Quotient
Aquatic species					
Vascular plants	Dissolved	0.00034 mg a.i./L (Myriophyllum spicatum, 14 day EC25)	0.000605 mg a.i./L	2	**3.56**
	Overspray	0.00099 mg a.i./L (Lemna gibba 72 hour EC50)	0.000605 mg a.i./L	2	**1.22**

Note: All the toxicity concentrations and EECs are mg a.i./L
1: EEC in 80 cm water depth
2: Aquatic plants: RQ = EEC/(EC50 ÷ 2)

Table 18 Refined Risk to Terrestrial and Aquatic Organisms: Spray Drift from Ground Field Sprayers and Aerial Application

Organism	Endpoint Value	Application Method (maximum rate)	[1] Spray Drift EEC	Correction factor	Risk [3]Quotient
Terrestrial species					
Vascular plants	Vegetative vigour ER25 Sunflower: 0.123 g a.i./ha	[2]Ground (7.5 g a.i./ha)	0.45 g a.i./ha	2	**7.32**
		[2]Aerial (5 g a.i./ha)	1.73 g a.i./ha	2	**28.13**
Aquatic species					
Vascular plants	0.00034 mg a.i./L (Myriophyllum spicatum, 14 day EC25)	[2]Ground (7.5 g a.i./ha)	0.00005625 mg a.i./L	2	0.33
	0.00034 mg a.i./L (Myriophyllum spicatum, 14 day EC25)	[2]Aerial (5 g a.i./ha)	0.0001438 mg a.i./L	2	0.42

Organism	Endpoint Value	Application Method (maximum rate)	[1]Spray Drift EEC	Correction factor	Risk [3]Quotient
	0.00099 mg a.i./L (Lemna gibba 72 hour EC50)	[2]Ground (7.5 g a.i./ha)	0.00005625 mg a.i./L	2	0.11
	0.00099 mg a.i./L (Lemna gibba 72 hour EC50)	[2]Aerial (5 g a.i./ha)	0.0001438 mg a.i./L	2	0.29

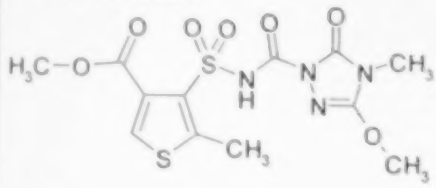
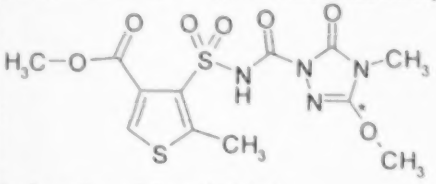
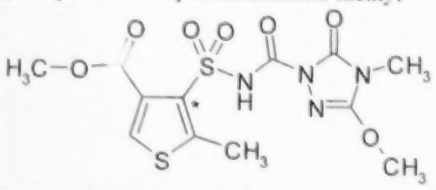
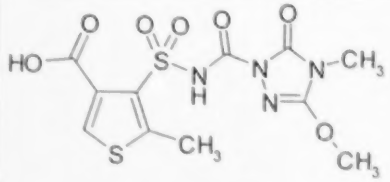
Note: All the toxicity concentrations and EECs are mg a.i./L

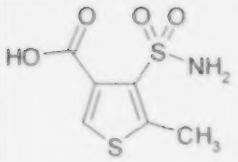
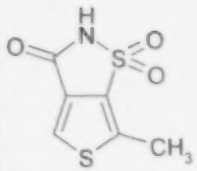
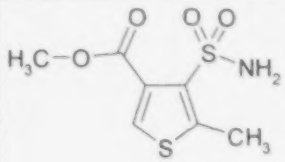
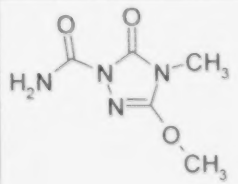
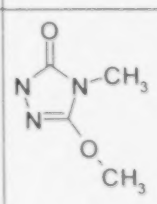
1: For aquatic species EEC in 80 cm water depth (fish and other organisms)

2: EEC for ground application = maximum rate x 6%; EEC for aerial application = maximum rate x 23%

3: Aquatic plants: RQ = EEC/(EC50 ÷ 2)

Table 19 Names, Structures and Occurrences of TCM and its Transformation Products

Name(s)	Structure	Occurrence
Thiencarbazone-methyl (parent) **Pseudonyms**-[BYH 18636, AE 1162464, BAY BYH 18636, BAY GELL 420, BAY GSE 18636, BAY LZR 8693, BAY NLL 6954]) **IUPAC name**- Methyl 4-[(4,5-dihydro-3-methoxy-4-methyl-5-oxo-1H-1,2,4-triazol-1-yl)carbonylsulfamoyl]-5-methylthiophene-3-carboxylate. Methyl 4-({[(3-methoxy-4-methyl-5-oxo-4,5-dihydro-1H-1,2,4-triazol-1-yl)carbonyl]amino}sulfonyl)-5-methylthiophene-3-carboxylate. Methyl 4-[(4,5-dihydro-3-methoxy-4-methyl-5-oxo-1H-1,2,4-triazol-1-yl)carboxamidosulfonyl]-5-methylthiophene-3-carboxylate. **CAS #**-317815-83-1	Unlabeled structure  [Dihydrotriazole-3-^{14}C]thiencarbazone-methyl  *= Location of the radiolabel. [Thiophene-4-^{14}C]thiencarbazone-methyl  *= Location of the radiolabel.	Parent
M01 (BYH 18636-carboxylic acid) **Pseudonyms**-[AE 1394083, GSE 28226, GSE 29091, FHW0117C, AP4, BP3, Carboxylic acid] **IUPAC name** 4-({[(3-Methoxy-4-methyl-5-oxo-4,5-dihydro-1H-1,2,4-triazol-1-yl)carbonyl]amino}sulfonyl)-5-methyl thiophene-3-carboxylic acid. 4-[(4,5-Dihydro-3-methoxy-4-methyl-5-oxo-1H-1,2,4-triazol-1-yl)carbonyl]amino}sulfonyl)-5-methyl thiophene-3-carboxylic acid. 4-[(4,5-Dihydro-3-methoxy-4-methyl-5-oxo-1H-1,2,4-triazol-1-yl)carboxamidosulfonyl]-5-methylthiophene-3-carboxylic acid **CAS #**-Not reported		Aerobic Soil Metabolism (Major) Anaerobic Soil Metabolism (Major) Anaerobic Aquatic Metabolism (Major) Aerobic Aquatic Metabolism (Major) Terrestrial Field Dissipation Study (Major)

M03 (BYH 18636-sulfonamide-carboxylic acid) **Pseudonyms**- AE 1395853, GSE 28098, GSE 28269, BP1, Sulfonamide-carboxylic acid; BYH 18636 acid sulfonamide **IUPAC name**-4-(Aminosulfonyl)-5-methylthiophene-3-carboxylic acid.) (CAS #-Not reported)		Hydrolysis (Minor) Anaerobic Aquatic (Major) Aerobic Soil Metabolism (Major) Anaerobic Soil Metabolism (Major) Anaerobic Aquatic Metabolism (Major) Aerobic Aquatic Metabolism (Major) Terrestrial Field Dissipation Study (Major)
M05 (BYH 18636-thieno-saccharine) **Pseudonyms**-[AE 1396119, GSE 26354, Thieno-saccharine] **IUPAC name**-6-Methylthieno[3,4-d]isothiazol-3(2H)-one 1,1-dioxide **CAS #**-Not reported		Aerobic Soil Metabolism (Minor)
M15 (BYH 18636-sulfonamide) **Pseudonyms**-AE 1364547, GSE 18448, BP2, Sulfonamide **IUPAC name**- Methyl 4-(aminosulfonyl)-5-methylthiophene-3-carboxylate **CAS #**-317815-81-9		Hydrolysis (Major) Aerobic Soil Metabolism (Major) Anaerobic Soil Metabolism (Minor) Anaerobic Aquatic Metabolism (Minor) Aerobic Aquatic Metabolism (Minor) Terrestrial Field Dissipation Study (Major)
M20 (BYH 18636-triazolinone carboxamide) **Pseudonyms**-[AE 1430601, GSE 28097, AP3, Triazolinone carboxylic acid, MMT amide] **IUPAC name**-3-Methoxy-4-methyl-5-oxo-4,5-dihydro-1H-1,2,4-triazole-1-carboxamide. **CAS #**-not reported		Aerobic Soil Metabolism (Minor) Terrestrial Field Dissipation Study (Minor)
M21(BYH 18636-MMT) **Pseudonyms**-[AE 1277106, GSE 12201, KOK 9972, AP2, MMT] **IUPAC name**-5-Methoxy-4-methyl-2,4-dihydro-3H-1,2,4-triazol-3-one **CAS #**-135302-13-5		Hydrolysis (Major) Aerobic Soil Metabolism (Major) Anaerobic Soil Metabolism (Major) Anaerobic Aquatic Metabolism (Major) Aerobic Aquatic Metabolism (Major) Terrestrial Field Dissipation Study (Major)

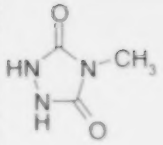
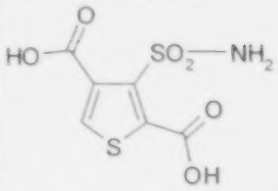
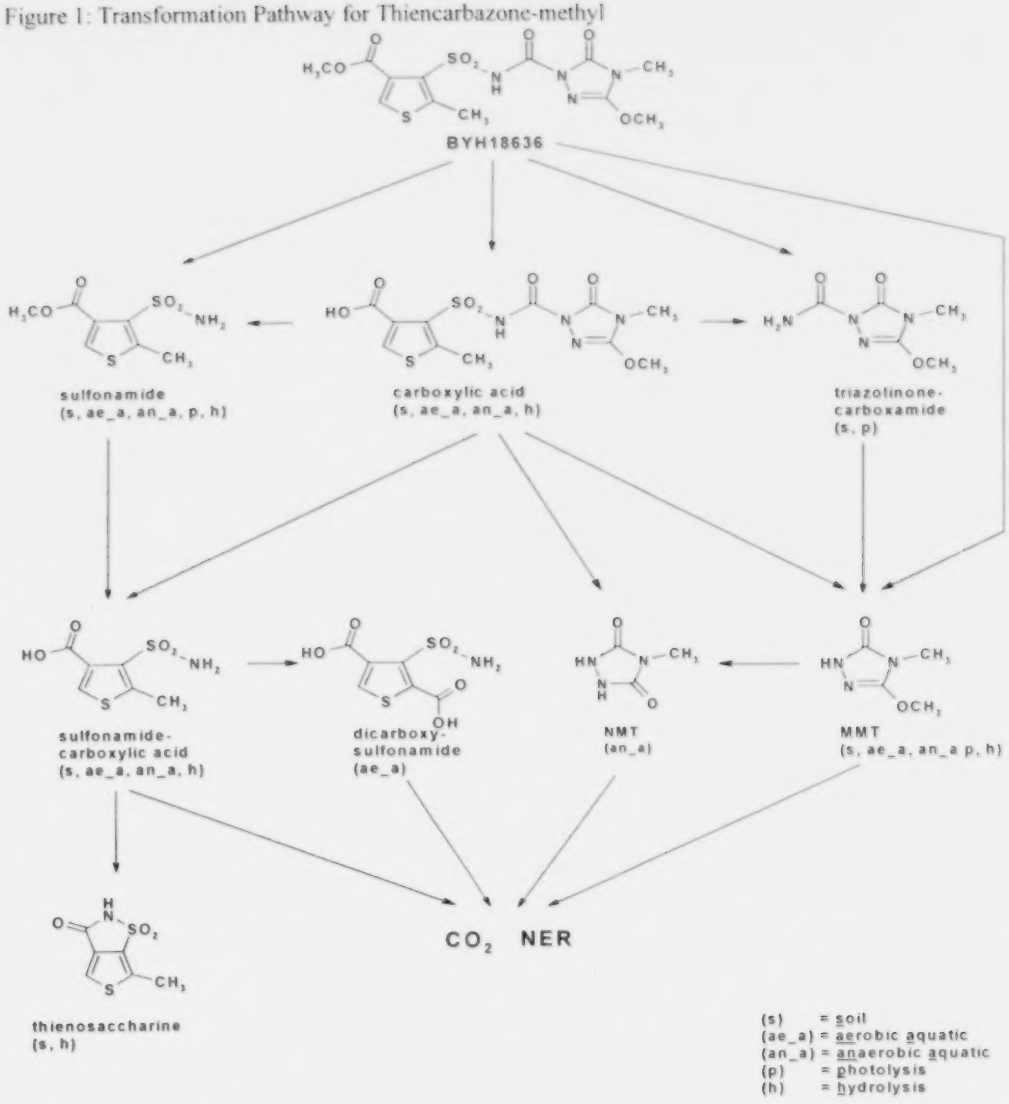
BYH 18636-NMT **Pseudonyms**-[N-methyltriazolinone, AE 0345336] **IUPAC name**-4-Methyl-1,2,4-triazolidine-3,5-dione **CAS #**-16312-79-1		Anaerobic Aquatic Metabolism (Major)
M25 (BYH18636-dicarboxy-sulfonamide) **Pseudonyms**-[FHW0119G, KATH4563-7-1, PX] **IUPAC name**-3-(Aminosulfonyl)thiophene-2,4-dicarboxylic acid **CAS #**-Not reported		Aerobic Aquatic Metabolism (Major)

Figure 1: Transformation Pathway for Thiencarbazone-methyl



Appendix II Supplemental Maximum Residue Limit Information—International Situation and Trade Implications

All of the specified Canadian MRLs are the same as those in the U.S. with the exception of poultry and hog commodities and fat of cattle, goats, horses and sheep. MRLs will be specified in Canada, however, in the U.S. the proposed uses of thiencarbazone-methyl will fall under category 3 of 40 CFR 180.6 (a). As well, the U.S. establishes MRLs on feed commodities whereas Canada does not.

Table 1 Differences Between Canadian MRLs and in Other Jurisdictions

Commodity	Canada (ppm)	U.S. (ppm)	Codex* (ppm)
Corn, sweet, stover	N/A	0.05	"Not reviewed by Codex"
Corn, field, stover	N/A	0.05	
Corn, pop, stover	N/A	0.02	
Corn, field, forage	N/A	0.04	
Wheat, hay	N/A	0.04	
Wheat, straw	N/A	0.03	
Wheat, forage	N/A	0.03	
Fat, meat and meat by-products of hogs	0.02	-	
Fat, meat and meat byproducts of poultry	0.02	-	
Fat of cattle, goats, horses and sheep	0.02	-	
Eggs	0.02		

* Codex is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

N/A = Not applicable

- No expectation of residues category 3 of 40 CFR 180.6 (a)

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data. For animal commodities, differences in MRLs can be due to different livestock feed items and practices.

Under the North American Free Trade Agreement (NAFTA), Canada, the United States and Mexico are committed to resolving MRL discrepancies to the broadest extent possible. Harmonization will standardize the protection of human health across North America and promote the free trade of safe food products. Until harmonization is achieved, the Canadian MRLs specified in this document are necessary. The differences in MRLs outlined above are not expected to impact businesses negatively or adversely affect international competitiveness of Canadian firms or to negatively affect any regions of Canada.

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1.0 Chemistry

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1408754 2007, Reference list - KIIIA1 6 Efficacy data and information (including value data) thiencarbazone-methyl (BYH 18636) isoxadifen-ethyl (AE F122006) tembotrione (AE 0172747) - SC547 herbicide, M-286309-01-1, DACO: Document L,Document O

1408756 2007, Reference list - KIIIA1 6 Efficacy data and information (including value data) thiencarbazone-methyl (BYH 18636) isoxadifen-ethyl (AE F122006) tembotrione (AE 0172747) - SC547 herbicide, M-286309-01-1, DACO: Document L,Document O

1410002 2007, [Dihydrotriazole-3-14C]BYH18636 and [thiophene-4-14C]BYH18636: Extraction efficiency of the residue analytical method for the determination of BYH18636 residues in animal matrices using aged radioactive residues, MEF-06/292, DACO: 7.2.1,7.2.4,IIA 4.

1410003 2007, Analytical method 00990 for the determination of residues of BYH 18636 and the metabolites in animal matrices, 00990, DACO: 7.2.1,7.2.4,8.2.2.4,IIA 4.3

1410004 2007, Independent laboratory validation of Bayer CropScience method no. 01022 for the determination of residues of BYH 18636 and its metabolite BYH 18636-MMT in animal matrices by LC/MS/MS, P/B 1138 G, DACO: 7.2.1,7.2.3,7.2.4,IIA 4.3

1410005 2007, Analytical method 01022 for the Determination of Residues of BYH18636 and BYH18636-MMT in Animal Matrices, MR-06/175 (Method No. 01022), DACO: 7.2.1,7.2.2,7.2.4,IIA 4.3

1410006 2006, Analytical method 00962 for the determination of residues of BYH18636 and the metabolites BYH18636-N-desmethyl and BYH18636-MMT-glucoside, and of AE 0001789 in/on plant matrices by HPLC-MS/MS, 00962, DACO: 7.2.1,7.2.4,IIA 4.3

1410007 2007, PAM I multiresidue protocol testing of BYH18636 and the metabolites, RAGSM007, DACO: 7.2.1,7.2.4,IIA 4.3

1410008 2006, Examination of the Applicability of DFG Method S19 for the Determination of the residues of BYH 18636, BYH 18636-N-Desmethyl and BYH 18636-MMT-glucoside, MR-06/110, DACO: 7.2.1,7.2.4,IIA 4.3

1410009 2007, Independent laboratory validation of Bayer CropScience method No. 00963 for the determination of residues of BYH 18636 and the metabolites BYH 18636-N-desmethyl and BYH 18636-MMT-glucoside in/on plant materials by LC/MS/MS, P/B 1125 G, DACO: 7.2.1,7

1410013 2006, [Dihydrotriazole-3-14C]BYH18636: Extraction Efficiency of the Residue Analytical Method for the Determination of BYH18636 Residues in Plant Matrices using Aged Radioactive Residues, MEF-05/504, DACO: 7.2.1,7.2.4,IIA 4.3

1410014 2007, Analytical method 00963 for the determination of residues of BYH18636 and the metabolites BYH18636-N-desmethyl and BYH18636-MMT-glucoside in/on plant matrices by HPLC-MS/MS, 00963, DACO: 7.2.1,7.2.2,7.2.4,IIA 4.3

1410075 2007, Storage stability of BYH18636 and the metabolites BYH18636-N-desmethyl and BYH18636-MMT-glucoside in plant matrices for 18 months - results for an interval of 0 to 12 months, MR-186/05, DACO: 7.3,IIA 6.1.1

1410076 2007, BYH 18636: Dairy Cattle Feeding Study, MR-06/095, DACO: 7.3,7.5,7.6,IIA 6.1.1,IIA 6.4.2

1408788 2007, Document A - Statement of the context in which the dossier is submitted for

thiencarbazone-methyl (BYH 18636), M-286358-01-1, DACO: Document A CBI

1408789 2007, Document C - Copies of existing or proposed labels for the plant protection product thiencarbazone-methyl & mefenpyr-diethyl OD70 herbicide (thiencarbazone-methyl 10 g/L & mefenpyr-diethyl 60 g/L) - (Specification: 102000014337) for whic..., M-28608

1408790 2007, Document D1 - Intended uses supported in the United States and Canada for which data have been provided for thiencarbazone-methyl (BYH 18636) and the plant protection product thiencarbazone-methyl & mefenpyr-diethyl OD70 herbicide (thien..., M-28610

1408791 2007, Document D1 - Intended uses supported in the United States and Canada for which data have been provided for thiencarbazone-methyl (BYH 18636) and the plant protection product thiencarbazone-methyl & mefenpyr-diethyl OD70 herbicide (thien..., M-28610

1408803 2007, Summary of exposure data and information of the plant protection product BYH18636 OD70 herbicide - AE1162464 WG63 herbicide in corn - SP10200015037 SC547 herbicide in corn, M-285911-01-1, DACO: 12.7,3.1.1,Document M,IIIA 1.1

1408804 2007, Summary of exposure data and information of the plant protection product BYH18636 OD70 herbicide - AE1162464 WG63 herbicide in corn - SP10200015037 SC547 herbicide in corn, M-285911-01-1, DACO: 12.7,3.1.1,Document M,IIIA 1.1

1408805 2007, Tier 2 summary of the residues data of the plant protection product BYH18636 OD70 herbicide - Specification: SP10200014337, M-285732-01-1, DACO: 12.7,3.1.1,Document M,IIIA 1.1

1408806 2007, Tier 2 summary of the residues data of the plant protection product BYH18636 OD70 herbicide - Specification: SP10200014337, M-285732-01-1, DACO: 12.7,3.1.1,Document M,IIIA 1.1

1408820 2007, Reference list - KIIIA1 5 Methods of analysis - thiencarbazone-methyl (BYH 18636), mefenpyr-diethyl (AE F107892) - OD70 herbicide, M-286317-01-1, DACO: Document J,Document L,Document O CBI

1408821 2007, Reference list - KIIIA1 5 Methods of analysis - thiencarbazone-methyl (BYH 18636), mefenpyr-diethyl (AE F107892) - OD70 herbicide, M-286317-01-1, DACO: Document J,Document L,Document O CBI

1410002 2007, [Dihydrotriazole-3-14C]BYH18636 and [thiophene-4-14C]BYH18636: Extraction efficiency of the residue analytical method for the determination of BYH18636 residues in animal matrices using aged radioactive residues, MEF-06/292, DACO: 7.2.1,7.2.4,IIA 4.

1410003 2007, Analytical method 00990 for the determination of residues of BYH 18636 and the metabolites in animal matrices, 00990, DACO: 7.2.1,7.2.4,8.2.2.4,IIA 4.3

1410004 2007, Independent laboratory validation of Bayer CropScience method no. 01022 for the determination of residues of BYH 18636 and its metabolite BYH 18636-MMT in

animal matrices by LC/MS/MS, P/B 1138 G, DACO: 7.2.1,7.2.3,7.2.4,IIA 4.3

1410005 2007, Analytical method 01022 for the Determination of Residues of BYH18636 and BYH18636-MMT in Animal Matrices, MR-06/175 (Method No. 01022), DACO: 7.2.1,7.2.2,7.2.4,IIA 4.3

1410006 2006, Analytical method 00962 for the determination of residues of BYH18636 and the metabolites BYH18636-N-desmethyl and BYH18636-MMT-glucoside, and of AE 0001789 in/on plant matrices by HPLC-MS/MS, 00962, DACO: 7.2.1,7.2.4,IIA 4.3

1410007 2007, PAM I multiresidue protocol testing of BYH18636 and the metabolites, RAGSM007, DACO: 7.2.1,7.2.4,IIA 4.3

1410008 2006, Examination of the Applicability of DFG Method S19 for the Determination of the residues of BYH 18636, BYH 18636-N-Desmethyl and BYH 18636-MMT-glucoside, MR-06/110, DACO: 7.2.1,7.2.4,IIA 4.3

1410009 2007, Independent laboratory validation of Bayer CropScience method No. 00963 for the determination of residues of BYH 18636 and the metabolites BYH 18636-N-desmethyl and BYH 18636-MMT-glucoside in/on plant materials by LC/MS/MS, P/B 1125 G, DACO: 7.2.1,7

1410013 2006, [Dihydrotriazole-3-14C]BYH18636: Extraction Efficiency of the Residue Analytical Method for the Determination of BYH18636 Residues in Plant Matrices using Aged Radioactive Residues, MEF-05/504, DACO: 7.2.1,7.2.4,IIA 4.3

1410014 2007, Analytical method 00963 for the determination of residues of BYH18636 and the metabolites BYH18636-N-desmethyl and BYH18636-MMT-glucoside in/on plant matrices by HPLC-MS/MS, 00963, DACO: 7.2.1,7.2.2,7.2.4,IIA 4.3

1410075 2007, Storage stability of BYH18636 and the metabolites BYH18636-N-desmethyl and BYH18636-MMT-glucoside in plant matrices for 18 months - results for an interval of 0 to 12 months, MR-186/05, DACO: 7.3,IIA 6.1.1

1410076 2007, BYH 18636: Dairy Cattle Feeding Study, MR-06/095, DACO: 7.3,7.5,7.6,IIA 6.1.1,IIA 6.4.2

1410101 2007, Magnitude of residues in/on Wheat Treated with One Application of the herbicide AE 1162464 01 OD07 with a 60 day PHI for Grain, RAGSP015, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.2

1410102 2007, Magnitude of residues in/on wheat treated with one application of the herbicide AE 1162464 01 OD07 with a 60 day PHI for grain, MR-06/154, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.2

1410106 2007, Magnitude of Residues in/on wheat processed commodities treated with one application of the herbicide AE 1162464 01 OD07, RAGSP016, DACO: 7.4.5,IIA 6.5.4

1410107 2005, Metabolism of [thiophene-4-14C]BYH18636 in Confined Rotational Crops, MEF-05/024, DACO: 7.3,7.8,IIA 6.6.2

1410108 2005, Metabolism of [dihydrotriazole-3-14C]BYH18636 in Confined Rotational

Crops, MEF-05/023, DACO: 7.3,7.8,IIA 6.6.2

1549579 2008, Thiencarbazone-monograph-vol3-B01-identity-OD70_WG63_SC547 IIIA1 1, N, DACO: 12.7 CBI

1549580 2008, Thiencarbazone-monograph-vol3-B01-identity-OD70_WG63_SC547 IIIA1 1, N, DACO: 12.7 CBI

1549581 2008, Thiencarbazone-monograph-vol3-B02-physchem-OD70_WG63_SC547 IIIA1 2, N, DACO: 12.7

1549582 2008, Thiencarbazone-monograph-vol3-B02-physchem-OD70_WG63_SC547 IIIA1 2, N, DACO: 12.7

1549583 2008, Thiencarbazone-monograph-vol3-B05-methods-OD70_WG63_SC547 IIIA1 4, N, DACO: 12.7 CBI

1549584 2008, Thiencarbazone-monograph-vol3-B05-methods-OD70_WG63_SC547 IIIA1 4, N, DACO: 12.7 CBI

1549585 2008, Thiencarbazone-monograph-vol4-confidential-information-OD70_WG63_SC547 IIIA1 1, N, DACO: 12.7 CBI

1549586 2008, Thiencarbazone-monograph-vol4-confidential-information-OD70_WG63_SC547 IIIA1 1, N, DACO: 12.7 CBI

1408920 2007, Document A - Statement of the context in which the dossier is submitted for thiencarbazone-methyl (BYH 18636), M-286358-01-1, DACO: Document A CBI

1408921 2007, Document C - Copies of existing or proposed labels for the plant protection product thiencarbazone-methyl & isoxadifen-ethyl WG63 herbicide (thiencarbazone-methyl 21 percent & isoxadifen-ethyl 42 percent) - Specification: AE1162464 WG63 ..., M-28608

1408922 2007, Document D1 - Intended uses supported in the Unites States and Canada for which data have been provided for thiencarbazone-methyl (BYH 18636) and the plant protection product thiencarbazone-methyl & isoxadifen-ethyl WG63 herbicide (thien..., M-28610

1408930 2007, Summary of exposure data and information of the plant protection product BYH18636 OD70 herbicide - AE1162464 WG63 herbicide in corn - SP10200015037 SC547 herbicide in corn, M-285911-01-1, DACO: 12.7,3.1.1,Document M,IIIA 1.1

1408931 2007, Summary of exposure data and information of the plant protection product BYH18636 OD70 herbicide - AE1162464 WG63 herbicide in corn - SP10200015037 SC547 herbicide in corn, M-285911-01-1, DACO: 12.7,3.1.1,Document M,IIIA 1.1

1408932 2007, Tier 2 summary of the residues data of the plant protection product AE1162464 WG63 herbicide - Specification: n/a, M-285734-01-1, DACO: 12.7,3.1.1,Document M,IIIA 1.1

1408933 2007, Tier 2 summary of the residues data of the plant protection product AE1162464 WG63 herbicide - Specification: n/a, M-285734-01-1, DACO:

12.7,3.1.1,Document M,IIIA 1.1

1410002 2007, [Dihydrotriazole-3-14C]BYH18636 and [thiophene-4-14C]BYH18636: Extraction efficiency of the residue analytical method for the determination of BYH18636 residues in animal matrices using aged radioactive residues, MEF-06/292, DACO: 7.2.1,7.2.4,IIA 4.

1410003 2007, Analytical method 00990 for the determination of residues of BYH 18636 and the metabolites in animal matrices, 00990, DACO: 7.2.1,7.2.4,8.2.2.4,IIA 4.3

1410004 2007, Independent laboratory validation of Bayer CropScience method no. 01022 for the determination of residues of BYH 18636 and its metabolite BYH 18636-MMT in animal matrices by LC/MS/MS, P/B 1138 G, DACO: 7.2.1,7.2.3,7.2.4,IIA 4.3

1410005 2007, Analytical method 01022 for the Determination of Residues of BYH18636 and BYH18636-MMT in Animal Matrices, MR-06/175 (Method No. 01022), DACO: 7.2.1,7.2.2,7.2.4,IIA 4.3

1410006 2006, Analytical method 00962 for the determination of residues of BYH18636 and the metabolites BYH18636-N-desmethyl and BYH18636-MMT-glucoside, and of AE 0001789 in/on plant matrices by HPLC-MS/MS, 00962, DACO: 7.2.1,7.2.4,IIA 4.3

1410007 2007, PAM I multiresidue protocol testing of BYH18636 and the metabolites, RAGSM007, DACO: 7.2.1,7.2.4,IIA 4.3

1410008 2006, Examination of the Applicability of DFG Method S19 for the Determination of the residues of BYH 18636, BYH 18636-N-Desmethyl and BYH 18636-MMT-glucoside, MR-06/110, DACO: 7.2.1,7.2.4,IIA 4.3

1410009 2007, Independent laboratory validation of Bayer CropScience method No. 00963 for the determination of residues of BYH 18636 and the metabolites BYH 18636-N-desmethyl and BYH 18636-MMT-glucoside in/on plant materials by LC/MS/MS, P/B 1125 G, DACO: 7.2.1,7

1410013 2006, [Dihydrotriazole-3-14C]BYH18636: Extraction Efficiency of the Residue Analytical Method for the Determination of BYH18636 Residues in Plant Matrices using Aged Radioactive Residues, MEF-05/504, DACO: 7.2.1,7.2.4,IIA 4.3

1410014 2007, Analytical method 00963 for the determination of residues of BYH18636 and the metabolites BYH18636-N-desmethyl and BYH18636-MMT-glucoside in/on plant matrices by HPLC-MS/MS, 00963, DACO: 7.2.1,7.2.2,7.2.4,IIA 4.3

1410075 2007, Storage stability of BYH18636 and the metabolites BYH18636-N-desmethyl and BYH18636-MMT-glucoside in plant matrices for 18 months - results for an interval of 0 to 12 months, MR-186/05, DACO: 7.3,IIA 6.1.1

1410076 2007, BYH 18636: Dairy Cattle Feeding Study, MR-06/095, DACO: 7.3,7.5,7.6,IIA 6.1.1,IIA 6.4.2

1410089 2007, Magnitude of Residues in/on Corn Treated with One Application of the Herbicide AE 1162464 03 WG63 with a 110 Day PHI for Grain, RAGSP017, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.10

1410090 2007, BYH 18636 450 SC and 63 WG - Magnitude of the Residue in/on Field Corn, Sweet Corn, and Pop Corn, RAGSM010, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.10

1410097 2007, Determination of the residues of AE 0001789 and BYH 18636 in/on corn after spraying of AE 1162464 02 SC39 A4 (450 SC) and BYH 18636 & AE F122006 (030 OD) in the field in Southern France, Spain, Italy, Greece and Portugal, RA-2590/05, DACO: 7.4.1,7.4

1410098 2007, Determination of the residues of AE 0001789, BYH 18636 in/on corn after spraying of AE 1162464 02 SC39 A4 (450 SC) and BYH 18636 & AE F122006 (030 OD) in the field in Germany, Northern France, United Kingdom and Belgium, RA-2589/05, DACO: 7.4.1,7.4.

1410103 2007, BYH 18636 450 SC and 63 WG - Request for Waiver of the Study of the Magnitude of the Residue in/on Field Corn Processed Commodities, RAGSP005, DACO: 7.4.5,IIA 6.5.4

1410104 2007, BYH18636 63 WG: Magnitude of the Residue in/on Soybean Processed Commodities, RAGSP011, DACO: 7.4.5,IIA 6.5.4

1410105 2007, BYH18636 63 WG - Magnitude of the Residue in/on Wheat Processed Commodities, RAGSP010, DACO: 7.4.5,IIA 6.5.4

1410113 2007, BYH18636 63 WG - Magnitude of the Residue in Wheat as a Rotational Crop (Limited Rotational Crop - Wheat), RAGSP008, DACO: 7.3,7.8,IIA 6.6.3

1410114 2007, BYH18636 63 WG - Magnitude of the Residue in Soybean Rotational Crops (9-Month and 12-Month Plant Back Intervals), RAGSP013, DACO: 7.3,7.8,IIA 6.6.3

1410115 2007, BYH18636 63 WG - Magnitude of the Residue in Soybeans (Rotational Crop Tolerance - 2 Month Plant-back Interval), RAGSP009, DACO: 7.3,7.8,IIA 6.6.3

1549583 2008, Thiencarbazone-monograph-vol3-B05-methods-OD70_WG63_SC547 IIIA1 4, N, DACO: 12.7 CBI

1549584 2008, Thiencarbazone-monograph-vol3-B05-methods-OD70_WG63_SC547 IIIA1 4, N, DACO: 12.7 CBI

1410026 2007, [Dihydrotriazole-3-14C]BYH18636: Distribution of the total radioactivity in male rats determined by quantitative whole body autoradiography, determination of the exhaled 14CO2, MEF-05/179, DACO: 4.5.9,IIA 5.1.1

1410027 2007, [Thiophene-4-14C]BYH18636: Distribution of the total radioactivity in male rats determined by quantitative whole body autoradiography, determination of the exhaled 14CO2, MEF-04/491, DACO: 4.5.9,IIA 5.1.1

1410029 2006, [Dihydrotriazole-3-14C]BYH 18636: Absorption, distribution, excretion and metabolism in the rat, MEF-06/049, DACO: 4.5.9,IIA 5.1.1

1410030 2006, [Thiophene-4-14C]BYH18636: Adsorption, distribution, excretion, and metabolism in the rat, MEF-05/176, DACO: 4.5.9, IIA 5.1.1

1410031 2007, BYH 18636-sulfonamide - Acute toxicity in the rat after dermal application, AT03211, DACO: 4.2.9,4.3.8,4.4.5,4.5.8,4.8,IIA 5.10

1410032 2007, BYH 18636-sulfonamide - Evaluation of potential dermal sensitization in the local lymph node assay in the mouse, SA 06367, DACO: 4.2.9,4.3.8,4.4.5,4.5.8,4.8,IIA 5.10

1410033 2007, BYH 18636-sulfonamide - Acute skin irritation/corrosion on rabbits - Activity ID: TXGSP002, AT03439, DACO: 4.2.9,4.3.8,4.4.5,4.5.8,4.8,IIA 5.10

1410034 2007, BYH 18636-sulfonamide - Acute eye irritation on rabbits - Activity ID: TXGSP001, AT03432, DACO: 4.2.9,4.3.8,4.4.5,4.5.8,4.8,IIA 5.10

1410035 2007, The non relevance of the BYH 18636 carboxylic acid (thiencarbazone-methyl-carboxylic acid), —285847-01-2, DACO: 4.2.9,4.3.8,4.4.5,4.5.8,4.8,8.5.1,8.6,IIA 5.10,IIA 7.13

1410036 2007, BYH 18636 - Acute toxicity in the rat after oral administration, AT03457, DACO: 4.2.1,IIA 5.2.1 CBI

1410037 2006, BYH 18636 (BYH 18636) - Acute toxicity in the rat after oral administration, AT01452, DACO: 4.2.1,IIA 5.2.1 CBI

1410038 2006, BYH 18636 - Acute toxicity in the rat after dermal application, AT01445, DACO: 4.2.2,IIA 5.2.2 CBI

1410039 2006, BYH 18636 - Acute inhalation toxicity in rats, AT01473, DACO: 4.2.3,IIA 5.2.3 CBI

1410040 2006, BYH 18636 - Acute skin irritation/corrosion on rabbits, AT01648, DACO: 4.2.5,IIA 5.2.4 CBI

1410041 2006, BYH 18636 - Acute eye irritation on rabbits, AT02437, DACO: 4.2.4,IIA 5.2.5 CBI

1410042 2006, BYH 18636 - Study for the skin sensitization effect in guinea pigs (guinea pigs maximization test according to Magnusson and Kligman), AT01388, DACO: 4.2.6,IIA 5.2.6 CBI

1410043 2006, BYH 18636 - 90-day toxicity study in the mouse by dietary administration, SA 03086, DACO: 4.3.1,IIA 5.3.2 CBI

1410044 2006, BYH 18636 - 90-day toxicity study in the rat by dietary administration, SA 02446, DACO: 4.3.1,IIA 5.3.2 CBI

1410045 2007, A 90-day toxicity feeding study in the beagle dog with technical grade BYH 18636, 201290-1, DACO: 4.3.2,IIA 5.3.3

1410046 2007, A chronic toxicity feeding study in the Beagle dog with technical grade BYH 18636, 201497-1, DACO: 4.3.2,IIA 5.3.4

1410047 2005, Waiver request for 21-day dermal study on BYH 18636, BCS 07-JZ-01, DACO: 4.3.5,IIA 5.3.7

1410048 2007, BYH 18636 - Salmonella/microsome test - Plate incorporation and preincubation method, AT03630, DACO: 4.5.4,IIA 5.4.1 CBI

1410049 2006, BYH 18636 (Project: BYH 18636) - Salmonella/microsome test - Plate incorporation and preincubation method, AT02274, DACO: 4.5.4,IIA 5.4.1

1410050 2007, BYH 18636 (Project: BYH 18636) - In vitro chromosome aberration test with chinese hamster V79 cells, AT03625, DACO: 4.5.6,IIA 5.4.2 CBI

1410051 2006, BYH 18636 (Project: BYH 18636) - In vitro chromosome aberration test with chinese hamster V79 cells, AT02499, DACO: 4.5.6,IIA 5.4.2

1410052 2007, BYH 18636 - V79/HPRT-test in vitro for the detection of induced forward mutations, AT03686, DACO: 4.5.5,IIA 5.4.3 CBI

1410053 2006, BYH 18636 - V79/HPRT-test in vitro for the detection of induced forward mutations, AT02752, DACO: 4.5.5,IIA 5.4.3

1410054 2006, BYH 18636 (Project: BYH 18636) - Micronucleus-test on the male mouse, AT01568, DACO: 4.5.7,IIA 5.4.4

1410055 2007, BYH 18636 - Combined chronic toxicity and carcinogenicity study in wistar rats (dietary administration for 2 years), AT03629, DACO: 4.4.2,4.4.4,IIA 5.5.2 CBI

1410056 2006, Carcinogenicity study of BYH 18636 in the mouse by dietary administration, SA 04062, DACO: 4.4.3,IIA 5.5.3

1410057 2006, BYH 18636 - Two-generation reproduction study in the Wistar rat by administration in the diet, AT03180, DACO: 4.5.1,IIA 5.6.1 CBI

1410058 2006, BYH 18636 - Developmental toxicity study in rats after oral administration, AT02339, DACO: 4.5.2,IIA 5.6.10 CBI

1410059 2006, BYH 18636 - Developmental toxicity study in the rabbit by gavage, SA 03350, DACO: 4.5.3,IIA 5.6.11 CBI

1410060 2006, An acute oral neurotoxicity screening study with technical grade BYH 18636 in Wistar rats, 201512, DACO: 4.5.12,IIA 5.7.1 CBI

1410061 2006, A subchronic neurotoxicity screening study with technical grade BYH 18636 in wistar rats, 201518, DACO: 4.5.13,IIA 5.7.4 CBI

1410062 2007, BYH 18636-N-desmethyl (AE 1417257) - 28-day toxicity study in the rat by dietary administration (Report of Study SA 06247), SA 06247, DACO: 4.8,IIA 5.8

1410063 2007, BYH 18636 N-desmethyl - Acute toxicity in the rat after oral administration - Activity ID: TXGSP055 (Report of Study T 1077241), AT03550, DACO: 4.8,IIA 5.8

1410064 2007, BYH 18636 N-desmethyl - (Project: BYH 18636) - V79/HPR - Test in vitro for the detection of induced forward mutations - TXGSP056 (Report of Study T 0076881), AT03687, DACO: 4.8,IIA 5.8

1410065 2007, BYH 18636 N-desmethyl - (Project: BYH 18636) - In vitro chromosome aberration test with chinese hamster V79 cells - TXGSP059 (Report of Study T 1076882), AT03678, DACO: 4.8, IIA 5.8

1410066 2006, BYH 18636 N-desmethyl - (Project: BYH 18636) - Salmonella/microsome test - Plate incorporation and preincubation method - TXGSP058 (Report of Study T 9076880), AT03497, DACO: 4.8,IIA 5.8

1410067 2007, BYH 18636-Sulfonamide - 28-day toxicity study in the rat by dietary

administration (Report of Study SA 06084), SA 06084, DACO: 4.8,IIA 5.8

1410068 2006, BYH 18636-sulfonamide - Acute toxicity in the rat after oral administration - Activity ID: TXGSP005 (Report of Study T 8076771), AT03210, DACO: 4.8,IIA 5.8

1410069 2006, BYH 18636-sulfonamide - (Project: BYH 18636) - Salmonella/microsome test - Plate incorporation and preincubation method - TXGSP003 (Report of study T 5076444), AT03605, DACO: 4.8,IIA 5.8

1410070 2007, BYH 18636-carboxylic acid - 90-day toxicity study in the rat by dietary administration (Report of Study SA 06035), SA 06035, DACO: 4.8,IIA 5.8

1410071 2006, BYH 18636-carboxylic acid (AE 1394083) - Acute toxicity in the rat after oral administration - Activity ID: TXGSP028 (Report of Study T 3076352), AT02902, DACO: 4.8,IIA 5.8

1410072 2005, BYH 18636-carboxylic acid - (Project: BYH 18636) - V79/HPRT-Test in vitro for the detection of induced forward mutations - TXGSX030 (Report of Study T 9073261), AT02038, DACO: 4.8,IIA 5.8

1410073 2005, BYH 18636-carboxylic acid (Project: BYH 18636) - In vitro chromosome aberration test with chinese hamster V79 cells - TXGSX031 (Report of Study T 8073260), AT01980, DACO: 4.8, IIA 5.8

1410074 2004, BYH 18636-carboxylic acid - (Project: BYH 18636) - Salmonella/microsome test - Plate incorporation and preincubation method - TXGSX0129 (Report of Study T 6073259), AT01522A, DACO: 4.8,IIA 5.8

1574626 2008, BYH 18636 SALMONELLA/MICROSOME TEST USING S9 OF MALE MICE PLATE INCORPORATION AND PREINCUBATION METHOD, TXGSP088, DACO: 4.5,4.5.4

1574627 2007, AN EVALUATION OF THE CARCINOGENICITY OF THIENCARBAZONE METHYL (BYH 18636), TXGSP080, DACO: 4.5,4.5.4

1408760 2007, SP102000016695 (636+747+isoxadifen SC) - Acute oral toxicity up and down procedure in rats, 21163, DACO: 4.6.1,IIIA 7.1.1

1408761 2007, SP102000016695 (636+747+isoxadifen SC) - Acute dermal toxicity study in rats - Limit test, 21164, DACO: 4.6.2,IIIA 7.1.2

1408762 2007, SP102000016695 (636+747+isoxadifen SC) - Acute inhalation toxicity study in rats - Limit test, 21165, DACO: 4.6.3,IIIA 7.1.3

1408763 2007, SP102000016695 (636+747+isoxadifen SC) - Primary skin irritation study in rabbits, 21167, DACO: 4.6.5,IIIA 7.1.4

1408764 2007, SP102000016695 (636+747+isoxadifen SC) - Primary eye irritation study in rabbits, 21166, DACO: 4.6.4,IIIA 7.1.5

1408765 2007, SP102000016695 (636+747+isoxadifen SC) - Dermal sensitization study in Guinea pigs (Buehler method), 21168, DACO: 4.6.6,IIIA 7.1.6

1408878 2006, BYH 18636 + Mefenpyr-diethyl OD 70 - Acute toxicity in the rat after oral

administration, AT03394, DACO: 4.6.1,IIIA 7.1.1

1408879 2006, BYH 18636 + Mefenpyr-diethyl OD 70 - Acute toxicity in the rat after dermal application, AT03393, DACO: 4.6.2,IIIA 7.1.2

1408880 2006, BYH 18636 + mefenpyr-diethyl OD 70 (thiencarbazone-methyl + mefenpyr-diethyl OD 10 + 60 g/l) - Acute inhalation toxicity in rats, AT03452, DACO: 4.6.3,IIIA 7.1.3

1408882 2006, BYH 18636 + Mefenpyr-diethyl OD 70 - Acute skin irritation/corrosion on rabbits, AT03304, DACO: 4.6.5,IIIA 7.1.4

1408883 2006, BYH 18636 + Mefenpyr-diethyl OD70 - Acute eye irritation on rabbits, AT03305, DACO: 4.6.4,IIIA 7.1.5

1408884 2006, BYH 18636 + mefenpyr-diethyl OD 70 - Evaluation of potential dermal sensitization in the local lymph node assay in the mouse, SA06185, DACO: 4.6.6,IIIA 7.1.6

1408955 2006, Isoxadifen + BYH 18636 WG 42 + 21 - Acute oral toxicity up and down procedure in rats, 20219, DACO: 4.6.1,IIIA 7.1.1

1408956 2006, Isoxadifen + BYH 18636 WG 42 + 21 - Acute dermal toxicity study in rats - Limit test, 20220, DACO: 4.6.2,IIIA 7.1.2

1408957 2006, Isoxadifen + BYH 18636 WG 42 + 21 - Acute inhalation toxicity in rats - Limit test, 20221, DACO: 4.6.3,IIIA 7.1.3

1408958 2006, Isoxadifen + BYH 18636 WG 42 + 21 - Primary skin irritation study in rabbits, 20223, DACO: 4.6.5,IIIA 7.1.4

1408959 2006, Isoxadifen + BYH 18636 WG 42 + 21 - Primary eye irritation study in rabbits, 20222, DACO: 4.6.4,IIIA 7.1.5

1408960 2006, Isoxadifen + BYH 18636 WG 42 + 21 - Dermal sensitization study in Guinea pigs (Buehler method), 20224, DACO: 4.6.6,IIIA 7.1.6

3.0 Environment

1521954 2005 BCS DER-BYH 18636 + AE F107892 OD 10 + 60 g/L Effects on ten species of non-target terrestrial plants: seedling emergence and seedling growth test (Tier 2). M-291524-01-1 DACO 9.8.4

1521955 2005, BCS DER-BYH 18636 + AE F107892 OD 10 + 60 g/L Effects on ten species of non-target terrestrial plants: vegetative vigour test (Tier 2). M-291527-01-1 DACO 9.8.4

1409986 2005, BYH18636: Hydrolytic degradation. M-259661-02-2 DACO 8.2.3.2

1410139 2005, Kinetic evaluation of the hydrolytic degradation of BYH 18636 (25 C, pH 9). M-286045-01-1 DACO 8.2.3.2

1410119 2005, BYH 18636: Phototransformation on soil. M-259443-01-2. DACO 8.2.3.3.1

1409987 2005, BYH18636: Phototransformation in water. M-244065-02-2. DACO 8.2.3.3.2

1409988 2005, BYH18636: Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation in water. M-093045-02-2. DACO 8.2.3.3.2

1410140 2005, BYH18636-MMT: Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation in water. M-274491-01-1. DACO 8.2.3.3.2

1410141 2005, BYH18636-dicarboxy-sulfonamide: Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation in water. M-274439-01-1 DACO 8.2.3.3.2

1410142 2005, BYH18636-sulfonamide-carboxylic acid: Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation in water. M-274499-01-1. DACO 8.2.3.3.2

1410143 2005, BYH18636-sulfonamide: Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation in water. M-274454-01-1. DACO 8.2.3.3.2

1410144 2005, BYH18636-carboxylic acid: Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation in water. M-274264-01-1. DACO 8.2.3.3.2

1409955 2005, BYH 18636 (AE 1162464): Calculation of the chemical lifetime in the troposphere. M-267793-01-2. DACO 8.2.3.3.3

1410116 2005, [Dihydrotriazole-3-14C] and [thiophene-4-14C]BYH 18636: Aerobic soil metabolism in one US soil. M-263213-01-2. DACO 8.2.3.4.2

1410117 2006, [Dihydrotriazole-3-14C] and [thiophene-4-14C] BYH 18636: Aerobic soil metabolism in four soils. M-276687-01-2. DACO 8.2.3.4.2

1410120 2007, Kinetic evaluation of the aerobic metabolism of BYH 18636, BYH 18636-carboxylic acid, BYH 18636-sulfonamide, BYH 18636-sulfonamide-carboxylic acid and BYH 18636 MMT in soil for modelling purposes. M-284770-01-1. DACO 8.2.3.4.2.

1410121 2007, Kinetic evaluation of the aerobic metabolism of BYH 18636, BYH 18636-carboxylic acid, BYH 18636-sulfonamide, BYH 18636-sulfonamide-carboxylic acid and BYH 18636 MMT in soil for comparison with triggers. M-284746-01-1. DACO 8.2.3.4.2

1410122 2006, BYH18636-triazolinone carboxamide: Aerobic soil degradation in 3 EU soils. M-276814-01-2. DACO 8.2.3.4.2

1410118 2006, [Dihydrotriazole-3-14C] and [thiophene-4-14C] BYH 18636: Anaerobic soil metabolism. M-274584-01-2. DACO 8.2.3.4.4

1410147 2007, [Dihydrotriazole-3-14C and thiophene-4-14C]BYH18636: Anaerobic aquatic metabolism. M-285668-01-1. DACO 8.2.3.5.4, 8.2.3.5.5, 8.2.3.5.6

1410133 2006, Adsorption/desorption of BYH 18636 on five soils. M-110732-01-2. DACO 8.2.4.2

1410134 2005, BYH 18636-triazolinone-carboxamide (AE 1430601): Estimation of the adsorption coefficient (Koc) on soil using high performance liquid chromatography. M-268082-01-2 DACO 8.2.4.2

1410135 2006, GSE12201: Adsorption/desorption on five soils. M-081509-01-2. DACO 8.2.4.2

1410136 2006, [14C]-BYH18636-sulfonamide-carboxylic acid: Adsorption to and desorption from five soils. M-263558-01-2. DACO 8.2.4.2

1410137 2006, GSE 18448: Adsorption/desorption on five soils. M-082278-01-2. DACO 8.2.4.2

1410138 2006, GSE28226: Adsorption/desorption in five soils. M-086868-01-2. DACO 8.2.4.2

1410215 2007, BYH 18636 carboxylic acid: Acute toxicity to the earthworm Eisenia fetida in artificial soil. M-259511-01-2. DACO 9.2.3.1

1410216 2007, BYH 18636 (tech.): Acute toxicity to earthworms (Eisenia fetida) tested in artificial soil. M-262506-01-2. DACO 9.2.3.1

1410212 2006, Acute toxicity of BYH 18636 a.i. tech. to the honeybee Apis mellifera L. under laboratory conditions. M-253914-01-2. DACO 9.2.4.2

1410214 2007, Toxicity to the predatory mite Typhlodromus pyri Scheuten (Acari, Phytoseiidae) in the laboratory BYH 18636 & AE 0001789 SC 225 + 225 g/l. M-270231-01-3. DACO 9.2.5

1410213 2007, Toxicity to the parasitoid wasp Aphidius rhopalosiphi (DeStephani-Perez) (Hymenoptera: Braconidae) in the laboratory - BYH 18636 & AE 0001789 SC 225 + 225 g/l. M-269942-01-2. DACO 9.2.6

1410190 2007, Acute toxicity of BYH 18636-sulfonamide to the waterflea Daphnia magna in a static laboratory test system - limit-test. M-282608-01-2. DACO 9.3.2

1410191 2007, BYH 18636-sulfonamide (tech.): Comparative toxicity of two different batches of the test-item to the waterflea Daphnia magna in a static laboratory test system. M-271240-01-2. DACO 9.3.2

1410192 2007, Acute toxicity of BYH 18636 sulfonamide to the Daphnia magna under static conditions. M-261931-02-1. DACO 9.3.2

1410193 2005, Acute toxicity of BYH 18636 technical to the Daphnia magna under static conditions. M-251028-01-2. DACO 9.3.2

1410194 2007, Chronic toxicity of BYH 18636 technical to the Daphnia magna under static renewal conditions. M-264057-02-1. DACO 9.3.3

1410180 2007, BYH 18636-MMT: Effects on the reproduction of the collembolans Folsomia candida. M-280552-01-2. DACO 9.3.4, 9.6.6, 9.9

1410181 2007, BYH 18636-sulfonamide-carboxylic acid: Effects on the reproduction of the collembolans Folsomia candida. M-280689-01-2. DACO 9.3.4, 9.6.6, 9.9

1410182 2007, BYH 18636-carboxylic acid: Influence on the reproduction of the collembola species Folsomia candida tested in artificial soil. M-262498-01-2. DACO 9.3.4, 9.6.6, 9.9

1410183 2007, BYH 18636 tech.: Influence on the reproduction of the collembola species Folsomia candida tested in artificial soil. M-275211-01-2. DACO 9.3.4, 9.6.6, 9.9

1410163 2006, Toxicity of BYH 18636 technical to the saltwater diatom Skeletonema costatum. M-281203-01-1. DACO 9.4.2, 9.4.3, 9.4.4

1410164 2006, BYH 18636 technical - Life-cycle toxicity test with mysids (Americamysis bahia). M-281198-01-2. DACO 9.4.2, 9.4.3, 9.4.4

1410165 2006, BYH 18636 technical - Acute toxicity to mysids (Americamysis bahia) under flow-through conditions. M-281936-01-1. DACO 9.4.2, 9.4.3, 9.4.4

1410166 2006, BYI 08330 technical - Acute toxicity to eastern oysters (Crassostrea virginica) under flow-through conditions. M-281935-01-1. DACO 9.4.2, 9.4.3, 9.4.4

1410167 2005, Acute toxicity of BYH 18636 technical to the sheepshead minnow (Cyprinodon variegatus) under static conditions. M-252017-01-1. DACO 9.4.2, 9.4.3, 9.4.4

1410168 2005, Acute toxicity of BYH 18636 technical to the sheepshead minnow (Cyprinodon variegatus) under static conditions. M-252017-01-1. DACO 9.4.2, 9.4.3, 9.4.4

1410186 2007, Acute toxicity of BYH 18636 sulfonamide to the rainbow trout (Oncorhynchus mykiss) under static conditions. M-262252-02-1. DACO 9.5.2.1, 9.5.2.3

1410187 2005, Acute toxicity of BYH 18636 technical to the rainbow trout (Oncorhynchus mykiss) under static conditions. M-252506-01-1. DACO 9.5.2.1, 9.5.2.3

1410188 2005, Acute toxicity of BYH 18636 technical to the bluegill (Lepomis macrochirus) under static conditions. M-257680-01-1. DACO 9.5.2.2, 9.5.2.3

1410189 2006, Early life stage toxicity of BYH 18636 technical to the fathead minnow (Pimephales promelas) under flow-through conditions. M-264063-01-1. DACO 9.5.3.1

1410151 2006, Acute oral toxicity for bobwhite quail (Colinus virginianus) with BYH 18636 a.s. M-261212-01-2. DACO 9.6.2.1, 9.6.2.2, 9.6.2.3

1410152 2006, Technical BYH 18636: A subacute dietary LC50 with northern bobwhite. M-278496-01-1. DACO 9.6.2.4, 9.6.2.5

1410153 2006, Technical BYH 18636: A subacute dietary LC50 with mallards. M-278504-01-1. DACO 9.6.2.6

1410154 2007, Effect of technical BYH 18636 on mallard reproduction. M-285456-01-1. DACO 9.6.3.1, 9.6.3.2, 9.6.3.3

1410155 2007, Effect of technical BYH 18636 on northern bobwhite reproduction. M-285465-01-1. DACO 9.6.3.1, 9.6.3.2, 9.6.3.3

1410195 2007, Toxicity of BYH 18636 technical to the blue-green alga Anabaena flos-aquae. M-264060-02-2. DACO 9.8.2, 9.8.3

1410196 2005, Toxicity of BYH 18636 technical to the freshwater diatom Navicula pelliculosa. M-257683-01-1. DACO 9.8.2, 9.8.3

1410197 2005, Toxicity of BYH 18636 sulfonamide to the green alga Pseudokirchneriella subcapitata. M-262576-01-1. DACO 9.8.2, 9.8.3

1410198 2005, Toxicity of BYH 18636 technical to the green alga - Pseudokirchneriella subcapitata. M-256477-01-1. DACO 9.8.2, 9.8.3

1501023 2007, BYH 18636 + AE F107892 OD 10 + 60 g/L Effects on ten species of non-target terrestrial plants: seedling emergence and seedling growth test (Tier 2). M-291524-01-1. DACO 9.8.4

1501025 2007, BYH 18636 + AE F107892 OD 10 + 60 g/L Effects on ten species of non-target terrestrial plants: vegetative vigour test (Tier 2). M-291527-01-1. DACO 9.8.4

1410169 2006, Evaluation of the post-emergence biological activity of AE 1394083, the carboxylic acid of thiencarbazone-methyl. M-274413-02-1. DACO 9.8.4

1410170 2006, Evaluation of the pre-emergence biological activity of AE 1394083, the carboxylic acid of thiencarbazone.methyl. M-274414-02-1. DACO 9.8.4

1410171 2007, Higher tier non target terrestrial plant study on the vegetative vigour test of 3 plant species determined under semi-field conditions. The phytotoxic effects of BYH 18636 + AE 0001789 SC 225 + 225 (thiencarbazone-methyl + cyprosulfamide). M-281484-02-2.DACO 9.8.4

1410172 2006, BYH 18636 + AE 0001789 SC 450 effects on eleven species of non-target terrestrial plants: vegetative vigour test (tier 2). M-281425-01-2. DACO 9.8.4

1410173 2007, Higher tier non target terrestrial plant study on the seedling emergence and growth of 4 plant species under semi-field conditions. The phytotoxic effects of TCM + CSA SC 225 + 225 G (thiencarbazone-methyl + cyprosulfamide SC 225 + 225 G/L). M-282887-02-2. DACO 9.8.4

1410174 2007, BYH 18636 + AE 0001789 SC 450 Effects on eleven species of non-target terrestrial plants: seedling emergence and seedling growth test (Tier 2). M-281379-01-2. DACO 9.8.4

1410203 2007, Toxicity of BYH 18636-dicarboxy-sulfonamide (a metabolite of BYH 18636) to duckweed (Lemna gibba G3) under static-renewal conditions. M-283800-01-1. DACO 9.8.5

1410204 2007, Toxicity of BYH 18636 MMT (a metabolite of BYH 18636) to duckweed (Lemna gibba G3) under static-renewal conditions. M-283972-01-1. DACO 9.8.5

1410205 2006, Toxicity of BYH 18636 sulfonamide (a metabolite of BYH 18636) to duckweed (Lemna gibba G3) under static-renewal conditions. M-284166-01-1. DACO 9.8.5

1410206 2006, Lemna gibba G3 growth inhibition test with BYH 18636 -sulfonamide-carboxylic acid under static conditions. M-273657-02-2. DACO 9.8.5

1410207 2005, Toxicity of BYH 18636 carboxylic acid to duckweed (Lemna gibba G3) under static-renewal conditions. M-258496-01-1. DACO 9.8.5

1410208 2007, BYH 18636 - comparative toxicity to three aquatic macrophytes during a 14-day exposure followed by a 14-day recovery period. M-284928-01-2. DACO 9.8.5

1410209 2007, Toxicity of BYH 18636 technical to the aquatic macrophyte, Myriophyllum spicatum, during a 14-day exposure and 14-day recovery period. M-285462-01-1. DACO 9.8.5

1410210 2007, Exposure and recovery with BYH 18636 technical to duckweed (Lemna gibba G3). M-285458-01-1. DACO 9.8.5

1410211 2006, Toxicity of BYH 18636 technical to duckweed (Lemna gibba G3) under static-renewal conditions. M-269681-01-1. DACO 9.8.5

1409980 2005, Henrys Law Constant of BYH 18636 (AE 1162464) at pH 4, pH 7, pH 9 and in water - Code: AE 1162464. M-258548-01-1. DACO 2.14.9

1410145 2006, BYH 18636-Sulfonamide – Biodegradation. M-266051-01-1. DACO 8.3.4.2

1410146 2006, BYH 18636 – Biodegradation. M-266049-01-1.. DACO 8.3.4.2

1410148 2007, Kinetic evaluation of the aerobic aquatic metabolism of BYH 18636, BYH 18636-carboxylic acid, BYH 18636-sulfonamide, BYH 18636-sulfonamide-carboxylic acid, BYH 18636-MMT and BYH 18636-dicarboxy-sulfonamide. M-284750-01-1. OECD IIA 7.8.3

1410149 2007, BYH18636-MMT: Aerobic aquatic degradation. M-281546-01-2. DACO 8.2.3.5.4

1410150 2006, BYH18636: Aerobic aquatic metabolism. M-262178-01-2. DACO 8.2.3.5.4

1410200 2007, Acute toxicity of BYH 18636-sulfonamide-carboxylic acid to larvae of Chironomus riparius in a 48 h static laboratory test system (limit-test). M-281523-01-2.DACO 9.3.4

1410201 2007, Acute toxicity of BYH 18636-carboxylic acid to larvae of Chironomus riparius in a 48 h static laboratory test system (Limit-Test). M-281173-01-2. DACO 9.3.4

1410202 2007, Acute toxicity of BYH 18636 (tech.) to larvae of Chironomus riparius in a

48 h static laboratory test system (Limit-Test). M-279507-01-2. DACO 9.3.4

1410217 2007, BYH 18636-MMT: Effects on reproduction and growth of earthworms Eisenia fetida in artificial soil. M-269458-01-2. DACO 9.2.3.1

1410218 2007, BYH 18636-sulfonamide-carboxylic acid: effects on reproduction and growth of earthworms Eisenia fetida in artificial soil. M-269975-01-2. DACO 9.2.3.1

1410219 2007, BYH 18636-sulfonamide: Sublethal toxicity to the earthworm Eisenia fetida in artificial soil. M-275605-01-2. DACO 9.2.3.1

1410220 2007, BYH 18636-carboxylic acid (technical): Effects on survival, growth and reproduction on the earthworm Eisenia fetida tested in artificial soil. M-260378-01-2. DACO 9.2.3.1

1410221 2007, BYH 18636 & AE 0001789 SC 450: Sublethal toxicity to the earthworm Eisenia fetida in artificial soil. M-277481-01-2. DACO 9.2.3.1

1410123 2007, Stability of BYH 18636 and its metabolites BYH 18636-carboxylic acid, BYH 18636-sulfonamide, BYH 18636 sulfonamidecarboxylic acid, BYH 18636-MMT, and BYH 18636-triazolinone carboxamide in soil during frozen storage. M-285671-01-1. DACO 8.3.2

1410124 2007, KineticeEvaluation of the dissipation of BYH 18636-carboxylic acid in soil based on field studies. M-284723-01-1. DACO 8.3.2

1410128 2007, Terrestrial field dissipation of BYH18636 in Ontario, Canada soil, 2005. M-285678-01-1. DACO 8.3.2

1410129 2007, Terrestrial field dissipation of BYH18636 in California soil, 2005. M-285682-01-1. DACO 8.3.2

1410130 2007, Terrestrial field dissipation of BYH18636 in Illinois soil, 2005. M-285673-01-1. DACO 8.3.2

1410131 2007, Terrestrial field dissipation of BYH18636 in Nebraska soil, 2005. M-285681-01-1. DACO 8.3.2

1410127 2007, Field dissipation of BYH18636 in three Canadian soils. M-285968-01-2. DACO 8.3.2

4.0 Value

1408869 DACOs 10.2.3.3, 10.3.2, 10.3.3, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, BYH18636 herbicide (thiencarbazone-methyl) for grassy and broadleaf weed control in spring and durum wheat- Canadian Value Package. 2520 pp.

1408948 DACOs 10.2.3.3, 10.3.2, 10.3.3, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, AE1162464 WG63 herbicide (thiencarbazone-methyl) for control of grassy and broadleaf weeds in corn- Canadian Value Package. 744 pp.